In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 18-1550V
Filed: July 8, 2024

ELIZABETH VALDEZ,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Michael Avrim Firestone, Marvin Firestone, MD, JD, and Associates, San Mateo, CA, for petitioner.
Nina Ren, U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

On October 9, 2018, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10, *et seq.* (2012),[2] alleging that she suffered small fiber neuropathy, neuropathy, paresthesia, weakness, and related complications, and/or a significant aggravation of chronic fatigue syndrome and fibromyalgia, following an influenza ("flu") vaccination that she received on October 10, 2015. (ECF No. 1.) However, petitioner subsequently amended her petition to instead allege that her symptoms constituted a significant aggravation of a pre-existing somatic symptom

[1] Because this document contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the document will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] Within this decision, all citations to § 300aa will be the relevant sections of the Vaccine Act at 42 U.S.C. § 300aa-10, *et seq.*

disorder.[3] (ECF No. 74.) For the reasons set forth below, I conclude that petitioner is *not* entitled to compensation and the petition is dismissed.

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a *causal link* between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

In many cases, however, the vaccine recipient may have suffered an injury *not* of the type covered in the Vaccine Injury Table. In such instances, an alternative means exists to demonstrate entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient's injury was "caused-in-fact" by the vaccination in question. § 300aa-13(a)(1)(B); § 300aa-11(c)(1)(C)(ii). In such a situation the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused the injury in question. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines ex rel. Sevier v. Sec'y of Health & Human Servs.*,

[3] The term "somatic" means "pertaining to or characteristic of the soma or body," with "soma" referring to "the body as distinguished from the mind." *Somatic*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=46193 (last visited June 26, 2024); *Soma*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=46186 (last visited June 26, 2024). The term "somatoform" refers to "physical symptoms that cannot be attributed to organic disease and appear to be of psychic origin." *Somatoform*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=46201 (last visited June 26, 2024). "Somatoform disorders" are a category of mental disorders characterized by somatoform symptoms that are not voluntary and not explained by any general medical condition, the effects of a psychoactive drug, or any other mental disorder. *Somatoform disorders*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=71228 (last visited June 26, 2024). Under the Fifth Edition of the American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders ("DSM-5"), "somatic symptom disorder" is the currently preferred diagnostic term for these types of disorders which are categorized as "somatic symptom disorder and related disorders." (Ex. 17, p. 32; Ex. A, pp. 29-30.) Somewhat confusingly, "somatic symptom disorder" also refers to a specific condition from which the broader category of conditions takes its name. This case involves that specific condition.

940 F.2d 1518, 1525 (Fed. Cir. 1991). Because petitioner's injury is not listed on the Vaccine Injury Table, petitioner must satisfy this burden of proof.

The showing of "causation-in-fact" must satisfy the "preponderance of the evidence" standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); *see also Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is "more probable than not" that the vaccination was the cause of the injury. *Althen*, 418 F.3d at 1279. The petitioner need not show that the vaccination was the sole cause of the injury or condition, but must demonstrate that the vaccination was at least a "substantial factor" in causing the condition, and was a "but for" cause. *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Thus, the petitioner must supply "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury;" the logical sequence must be supported by "reputable medical or scientific explanation, *i.e.*, evidence in the form of scientific studies or expert medical testimony." *Althen*, 418 F.3d at 1278; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). A petitioner may not receive a Vaccine Program award based solely on his or her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1).

In what has become the predominant framing of this burden of proof, the *Althen* court described the "causation-in-fact" standard, as follows:

> Concisely stated, Althen's burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury. If Althen satisfies this burden, she is entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine.

Althen, 418 F.3d at 1278 (citations omitted). The *Althen* court noted that a petitioner need not necessarily supply evidence from medical literature supporting petitioner's causation contention, so long as the petitioner supplies the medical opinion of an expert. *Id*. at 1279-80. However, that expert's opinion must be based upon "sound and reliable" scientific explanation. *Boatmon v. Sec'y of Health & Human Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019) (quoting *Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs*., 35 F.3d 543, 548-49 (Fed. Cir. 1994)). The *Althen* court also indicated that, in finding causation, a Program factfinder may rely upon "circumstantial evidence," which the court found to be consistent with the "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." 418 F.3d at 1280.

A petitioner may also allege that a vaccine caused a "significant aggravation" of a pre-existing condition. The Vaccine Act defines a significant aggravation as any change for the worse in a pre-existing condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health. § 300aa-33(4). Where a petitioner in an off-Table case is seeking to prove that a vaccination aggravated a pre-existing injury, petitioners must also address three *additional* factors. *See Loving v. Sec'y of Health & Human Servs.*, 86 Fed. Cl. 135, 144 (Fed. Cl. 2009) (combining the first three *Whitecotton* factors for claims regarding aggravation of a Table injury with the three *Althen* factors for off table injury claims to create a six-part test for off-Table aggravation claims); *see also W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1357 (Fed. Cir. 2013) (applying the six-part *Loving* test.). The additional *Loving* factors require petitioners to demonstrate aggravation by showing: (1) the vaccinee's condition prior to the administration of the vaccine, (2) the vaccinee's current condition, and (3) that the vaccinee's current condition constitutes a "significant aggravation" of the condition prior to the vaccination. *W.C.*, 704 F.3d at 1357.

II. Procedural History

This case was initially assigned to another special master. (ECF No. 4.) In December of 2018, petitioner filed an affidavit marked Exhibit 1 and medical records marked as Exhibits 2-8. She also filed a self-completed VAERS submission at Exhibits 9 and 11, an affidavit by her husband as Exhibit 10, and additional medical records at Exhibit 12. (ECF Nos. 7-8.) She filed her Statement of Completion on December 10, 2018. (ECF No. 9.) Respondent's medical review of the case began in August of 2019, and based on that review, respondent requested that petitioner file additional medical records. (ECF No. 16.) Petitioner filed the requested medical records and an amended Statement of Completion in September of 2019. (ECF Nos. 19-20.) The case was reassigned to the undersigned in the interim. (ECF Nos. 17-18.)

Respondent filed his Rule 4 Report, recommending against compensation, on March 23, 2020. (ECF No. 27.) Respondent disputed that petitioner's medical records supported her allegation that she suffered either any form of neuropathy following her vaccination or any significant aggravation of fibromyalgia and/or chronic fatigue syndrome. (*Id.* at 22-23.) Respondent also disputed that she had demonstrated vaccine causation of any of her alleged conditions. (*Id*. at 23-27.)

Following the filing of respondent's report, I held a follow up status conference. (ECF No. 28.) I advised that, based on my preliminary review of the medical records, it appeared that petitioner was an unreliable historian, that there was no objective evidence to support the alleged small fiber neuropathy or fibromyalgia, and that the medical records appeared to preponderantly establish the presence of a somatoform disorder. (*Id*. at 1-2.) Accordingly, before I would conclude petitioner had a reasonable basis to proceed based on either fibromyalgia or small fiber neuropathy, I required petitioner as a threshold matter to have a qualified expert establish either (a) that petitioner does not have a somatoform disorder or (b) that her somatoform disorder cannot explain her allegedly vaccine caused symptoms. (*Id*. at 2.) In response,

petitioner's counsel requested the opportunity to explore whether petitioner could establish that her somatoform disorder *itself* was significantly aggravated by her vaccination. (*Id*.)

Petitioner then filed additional medical records (Exhibits 15-16, 27-33) and an expert report with supporting materials by neurologist and psychiatrist W. Curt LaFrance, Jr., M.D., M.P.H. (Exhibit 17-26).[4] (ECF Nos. 30, 37, 42-43, 45, 47, 53.) Dr. LaFrance opined that petitioner had suffered symptoms of a somatic symptom disorder that were worsened by her flu vaccination. (Ex. 17, pp. 32-33.) He indicated that her medical work up "does not reveal a medical or neurological etiology for her symptoms." (*Id*. at 32.) Petitioner filed a further Statement of Completion on June 3, 2021. (ECF No. 48.) In September of 2021, respondent filed responsive expert reports by psychiatrist Joel Dimsdale, M.D. (Exhibit A) and neurologist Mark Bromberg, M.D., Ph.D. (Exhibit C). (ECF Nos. 51-52.) Respondent's experts agreed that petitioner likely suffered a somatic symptom disorder, rather than any neurologic condition, but disagreed that petitioner's flu vaccine played a causal role in her subsequent medical course.

On December 9, 2021, I held a follow up status conference to discuss the experts' reports. (ECF No. 54.) I observed that "it appears that the crux of the competing opinions – between Dr. LaFrance and Dr. Dimsdale – concerns the distinction between a preceding versus precipitating event in the context of a somatic symptom disorder." (*Id*. at 1.) I requested that, in addition to any other issues the parties intended to address, Drs. LaFrance and Dimsdale address in greater depth what factors contribute to whether an event constitutes a precipitating event. (*Id*.) I also advised that I was not aware of any prior precedent establishing that a strictly psychological injury could be a cognizable injury under the Vaccine Act and prompted the parties to consider that legal issue.[5] (*Id*. at 1-2.)

Thereafter, the parties exchanged further reports by Drs. LaFrance and Dimsdale, but not Dr. Bromberg. (ECF Nos. 35, 59, 61-62; Exs. 34-55, E.) After review of these reports, I held a further status conference on August 26, 2022. (ECF No. 63.) During the conference, I confirmed that petitioner intended to continue pursuing her claim as a significant aggravation of a somatoform disorder and that she did not wish to raise any additional arguments in response to Dr. Bromberg's report.[6] (*Id*. at 1.) The parties agreed to proceed with a ruling on the written record. (*Id*.)

[4] Dr. LaFrance's report and supporting materials were misfiled and struck multiple times.

[5] Although the parties did subsequently include some discussion of this issue in their briefs, because I have otherwise concluded for the reasons discussed below that there is not preponderant evidence that petitioner's vaccination actually caused a significant aggravation of her psychological condition, it is not ultimately necessary to reach that question.

[6] I have reviewed Dr. Bromberg's report. However, it is not necessary to discuss Dr. Bromberg's report because the parties have ultimately agreed that petitioner has not suffered any neurologic condition resulting from her vaccination. As discussed below, in his second report, Dr. LaFrance specifically agreed on petitioner's behalf that Dr. Bromberg was correct to conclude that petitioner's flu vaccine had not resulted in any "physical damage." (Ex. 34, p. 4.)

In January of 2023, petitioner subsequently filed additional medical records (ECF No. 66; Exs. 56-57) and a motion for a ruling on the written record (ECF No. 69). Respondent initially filed his response in April of 2023. (ECF No. 71.) However, petitioner then filed an amended petition conforming the allegations of her petition to the injury and theory she had pursued through Dr. LaFrance's opinion. (ECF No. 74.) Respondent filed an amended response to petitioner's motion on June 22, 2023. (ECF No. 75.) Petitioner filed her reply on July 28, 2023. (ECF No. 77.)

In light of the above, I have determined that the parties have had a full and fair opportunity to present their cases and that it is appropriate to resolve entitlement on the existing record. *See* Vaccine Rule 8(d); Vaccine Rule 3(b)(2); *see also Kreizenbeck v. Sec'y of Health & Human Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020) (noting that "special masters must determine that the record is comprehensive and fully developed before ruling on the record"). Accordingly, this matter is now ripe for resolution.

III. Factual History

Petitioner has an extensive medical history wherein many efforts were made to hopefully discover the etiology of her various symptoms. In litigating this claim, however, petitioner has acknowledged through her expert that she suffered a somatic symptom disorder, that her symptoms had no organic basis, and that her vaccination caused no physical harm. (Ex. 34, pp. 3-4.) Moreover, the nature of her somatic symptom disorder is such that she has persistently initiated contact with her treating physicians regarding her various symptoms, generating a large quantity of medical records. Thus, in the interest of brevity and consistent with the expert opinions offered in the case, this summary presents petitioner's history with the full benefit of hindsight as the course of a somatic symptom disorder. Nonetheless, although the resulting summary will not necessarily capture every symptom report or the efforts undertaken to determine their cause, I have reviewed the entirety of the medical records.

a. Pre-vaccination medical records

In April of 2006, petitioner saw neurologist Dr. John Bissell for a hospital follow up visit for what was assessed as late effects of a stroke. (Ex. 14, p. 14.) Petitioner reported that she continued to feel dizzy, dysphagic, and numb on the left side. She presented in a wheelchair but was able to ambulate with a cane or walker, despite a left-sided limp. She also reported experiencing double vision. Dr. Bissel assessed dysphagia and late effect of stroke, but he noted that risk factors for stroke were controlled. (*Id.*)

Petitioner returned to Dr. Bissel on May 15, 2006, with complaints of blurry vision, headaches, and insomnia. (Ex. 14, p. 28.) It was noted that petitioner's eye exam was normal, and a repeat MRI of her brain was unremarkable. Petitioner's neurologic examination revealed difficulty with finger to nose testing and continued

difficulty ambulating. Dr. Bissel suspected vertiginous disorder due to labyrinthine dysfunction with functional overlay, but his primary diagnosis was dizziness. Notes for a telephone encounter on June 16, 2006, include reports of difficulty swallowing and speaking. (*Id.* at 37.)

Petitioner's next appointment with Dr. Bissel was on August 7, 2006. (Ex. 14, p. 45.) It is noted that petitioner had recently gone to the emergency department for paroxysmal supraventricular tachycardia ("PSVT") and had felt weak ever since. It was further noted that, by that point, petitioner had been on disability for ten years with a highly sedentary lifestyle. Petitioner's neurologic examination was normal, despite initial limping and apparent gait instability. Dr. Bissel's diagnosed petitioner with somatoform disorder. He noted that there was no evidence of neurologic disease and that he did not believe petitioner's prior episodes were caused by a stroke. (*Id.*)

In January of 2011, petitioner presented to Kaiser Permanente for a regular appointment with her primary care physician, Dr. Serene Tran. (Ex. 2, p. 37.) Petitioner's medical history was notable for somatoform disorder with stroke-like symptoms, chest pain, and palpitations. Petitioner reported improvement in her strength and ability to walk without support; however, she continued to complain of chest pain and palpitation when she is upset. It is noted that petitioner could not tolerate many medications "due to nonspecific symptoms." A review of symptoms revealed achiness and stiffness in her fingers, especial in the morning and at night, as well as anxiety. Petitioner's neurologic exam was normal. (*Id.*) Later that month, on January 31, 2011, petitioner returned to Dr. Tran with no new complaints, and her somatoform disorder was noted to be stable. (*Id.* at 39.)

During a pre-operative examination on November 19, 2012, in preparation for a cervical loop electrosurgical excision procedure ("LEEP"), it was noted that petitioner had a history of reaction to multiple anesthetic agents. (Ex. 2, p. 364.) Petitioner was referred to Dr. Christopher Jakle on November 27, 2012, for an evaluation of her alleged reaction to several medications. (*Id.* at 341.) Petitioner reported adverse reactions, including dyspnea, dizziness, vomiting, and weakness, following receipt of carpal tunnel injections, containing lidocaine[7] and dexamethasone,[8] and an epidural. Dr. Jakle described petitioner as a "[v]ery suggestive individual who anticipates reactions to many medicines and procedures" and suggested that her past reactions were most likely vasovagal. (*Id.*)

[7] Lidocaine is a drug that is typically applied topically for its anesthetic, sedative, analgesic, anticonvulsant, and cardiac depressant properties. *Lidocaine*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=28237 (last visited June 27, 2024).

[8] Dexamethasone is synthetic glucocorticoid that is also applied topically as an anti-inflammatory or used orally in replacement therapy for adrenocortical insufficiency, as an anti-inflammatory and immunosuppressant, and as an antiemetic in chemotherapy. *Dexamethasone*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=13599 (last visited June 27, 2024).

On December 14, 2012, petitioner saw Dr. Train with complaints of fainting. (Ex. 2, pp. 442-43.) Petitioner described an episode of lightheadedness and blurry vision while walking, which was mostly resolved after lying down. (*Id.* at 441.) She reported feeling tightness in the chest and numbness on the face for a few minutes following the episode. Additionally, petitioner reported stress and low back pain with no radiation or neurologic symptoms. (*Id.*) Petitioner's neurologic examination was normal, but her physical examination revealed back pain with motion and tenderness along the paraspinal muscle in the low back. (*Id.* at 442.) Dr. Tran assessed lumbosacral strain and dizziness of unknown etiology; however, she questioned whether the condition could have been a side effect of petitioner's hypertension medication, dehydration, or anxiety. (*Id.* at 443.)

On March 21, 2013, petitioner presented to the emergency department with multiple complaints. (Ex. 2, p. 531.) She reported a gradual onset of palpitations, lightheadedness, chest discomfort, nausea, and generalized weakness. She described the chest discomfort as substernal non-radiating pressure without jaw pain and reported that the lightheadedness was worse when standing up. She denied associated headache, fever, chills, abdominal pain, urinary complaints, or focal weakness. (*Id.*) Petitioner's physical and neurologic examinations were normal. (*Id.* at 533-34.) Petitioner's symptoms improved after receiving IVF fluids, and all diagnostic testing was normal. (*Id.* at 535-36.) The attending physician diagnosed petitioner with "symptoms likely secondary to palpitations from mild dehydration" and explained, "I do not suspect that this patient has a life-threatening etiology to the presentation today requiring further diagnostic testing or evaluation." (*Id.*)

Petitioner complained of intermittent palpitations in December of 2013. (Ex. 2, p. 908.) She reported that her heart rate remained elevated for 20 minutes or so and that she felt as if she could pass out due to the palpitations; however, she reported more recently feeling tired without palpitation or chest pain. (*Id.*) She admitted that she may have been stressed due to the holidays. (*Id.* at 909.) Dr. Tran assessed PSVT, ordered labs, and advised petitioner to rest, hydrate, and reduce her stress. (*Id.* at 910.)

On April 9, 2014, petitioner was seen by Dr. Dorothy Hong for upper back pain that radiated to her chest. (Ex. 2, pp. 988-89.) Petitioner reported palpitations, chest pain with movement, a burning sensation in the epigastrium, and tiredness. (*Id.*) She further detailed her history of palpitations, noting that she usually experiences one-to-two episodes per year, which include palpitations, tachycardia, lightheadedness, chest discomfort, and fatigue with no clear trigger. (*Id.* at 989.) She explained that the episodes generally last for a few minutes with the longest episode lasting two hours. (*Id.*) Dr. Hong assessed petitioner's chest pain as multifactorial and provided a different diagnosis of gastroesophageal reflux disease ("GERD"), myofascial pain, or PSVT. (*Id.* at 992-93.) She noted that petitioner's labs were normal, and EKG performed that day revealed no evidence of acute coronary syndrome. Dr. Hong directed petitioner to follow up regarding an ablation procedure and reduce her stress. (*Id.*) Two days later, on April 11, 2014, petitioner presented for an urgent visit with gynecologist Dr. Sarah Fletcher. (*Id.* at 1011.) Petitioner reported a two-week history of intermittent abdominal

pain and cramping; however, Dr. Fletcher doubted that petitioner's pain had a gynecologic origin. (*Id.* at 1012.)

Petitioner presented for a dermatology appointment on April 17, 2014. (Ex. 2, pp. 1029-30.) During this encounter, petitioner received an injection of Kenalog.[9] (*Id*. at 1030.) Immediately thereafter, petitioner experienced weakness and dizziness. She reported a history of allergic reaction to dexamethasone with similar symptoms of weakness and dizziness. Her dermatologist questioned whether petitioner experienced an allergic reaction to Kenalog, given that her symptoms were not consistent with an acute allergic reaction. He also questioned her previous allergic reaction to Dexamethasone. Somatoform disorder or vasovagal symptoms were on her differential. (*Id.*)

On April 28, 2014, petitioner presented to the emergency department with complaints of weakness following an episode of tachycardia. (Ex. 2, p. 1043.) She reported an uptick in the frequency of episodes of palpitations and suggested that this could be why she felt more tired than normal. (*Id.*) Petitioner's examination and workup were normal. (*Id.* at 1044-45.) The attending physician determined that petitioner's symptoms were consistent with benign palpitations, and she was discharged home in an improved condition. (*Id.* at 1045.)

Petitioner underwent an ablation for typical atrioventricular nodal re-entry tachycardia without complications on May 5, 2014. (Ex. 2, p. 1096.) In a telephone encounter that took place two days after the procedure, on May 7, 2014, petitioner complained of lightheadedness, dizziness when standing, nausea, coldness in her feet, and intermittent chest pain since the ablation. (*Id.* at 1146-47, 1151.) She reported a blood pressure of 111/64 and a heart rate of 67 bpm. (*Id.* at 1146-47.) Given her recent procedure and the nature and severity of her reported symptoms, petitioner was directed to go to the emergency room. (*Id.* at 1147, 1151.)

The following day, on May 8, 2014, petitioner reported continued but improved lightheadedness; however, she also reported new symptoms of shortness of breath with activity, chest soreness when breathing deeply, "heaviness" in the left arm, and numbness in the left foot and left side of the face. (*Id.* at 1155, 1164.) She further reported a history of "mild stroke." (*Id.*) That same day, she presented to the emergency department with complaints of left arm weakness and left-sided facial numbness and swelling. (*Id.* at 1166-69.) It was also noted that petitioner "has multiple comatic complaints that are chronic." (*Id.*) Petitioner underwent a brain MRI and MRA without contrast, which showed no acute intracranial process. (*Id.* at 1171-73.) Neurologist Dr. Jason Chang determined that there was no evidence of neurologic disease, beyond small vessel disease, and that petitioner's reports did not constitute

[9] Kenalog is a triamcinolone acetonide that is applied topically as an anti-inflammatory or administered by intra-articular, intradermal, intralesional, intramuscular, intrabursal, or tendon sheath injection as an anti-inflammatory and immunosuppressant. *Kenalog*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=26808 (last visited June 27, 2024); *Triamcinolone acetonide*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=114887 (last visited June 26, 2024).

transient ischemic attack or stroke. (*Id.* at 1171.) He also noted that, although petitioner claimed to have a history of stroke, an MRI performed in 2006 was negative for stroke. (*Id.* at 1169, 1171-73.) Dr. Chang stated, "Unclear if this is a psychosomatic presentation based on her past medical history." (*Id.* at 1169.) On May 9, 2014, petitioner reported that her shortness of breath, chest soreness, and lightheadedness had resolved. (*Id.* at 1156.) Her EKG results were normal. (*Id.*)

On May 14, 2014, petitioner reported continued fatigue and palpitations. (Ex. 2, p. 1213.) An event monitor was ordered to track the episodes in an attempt to uncover whether these reported episodes were related to recurrence of arrhythmia, the ablation, or some other medical issue. (*Id.* at 1207-13.) Two days later, on May 16, 2014, petitioner reported continued palpitations, lightheadedness that was worse when standing up, shortness of breath with exertion, and chest pain that was unrelated to exertion. (*Id.* at 1216.) She described difficulty walking due to fatigue and lightheadedness. At-home blood pressure checks were normal. (*Id.*)

Petitioner's next encounter was on June 2, 2014. (Ex. 2, pp. 1269-70.) She reported lightheadedness, weakness, headache, and intermittent palpitations since her ablation. (*Id.*) She further complained of continued fatigue. (*Id.* at 1290.) Dr. Tran deferred making an assessment as to petitioner's heart condition until her monitoring period concluded but determined that petitioner's fatigue was likely due to normal recovery after her ablation. (*Id.* at 1270-71.) A chest x-ray showed no acute cardiopulmonary disease, and an echocardiogram was unremarkable. (*Id.* at 1276-78, 1282-87.) A progress note recorded on June 17, 2014, reported that the event monitor did not "auto capture" any triggered events for the period of May 14, 2014, through June 14, 2014. (*Id.* at 1199-200.) Petitioner reported 37 triggered events: 9 episodes with no associated symptoms, 16 episodes with associated "palpitations," 2 episodes of lightheadedness, and 10 episodes of dizziness. (*Id.* at 1199-200.) Throughout these reported episodes, petitioner's heart rate did not drop below 59 bpm or rise above 102 bpm. (*Id.*) Dr. Vu Ta determined that the events did not constitute significant arrhythmia and explained that, although it was not clear what was causing petitioner's symptoms, her symptoms did not appear to be the result of a cardiac issue. (*Id.* at 1119, 1298.)

On June 23, 2014, petitioner presented to Dr. Ta for an urgent follow up regarding her shortness of breath, intermittent palpitations, and generalized fatigue. (Ex. 2, p. 1302.) Petitioner was diagnosed with dyspnea of unknown etiology; however, Dr. Ta noted that the symptoms were probably not cardiac-related. (*Id.* at 1305.)

Petitioner attempted to call her primary care physician on September 3, 2014, with complaints of palpitations, discomfort, and difficulty breathing. (Ex. 2, pp. 1332-33.) Petitioner indicated that she did not want to go to the emergency department for her symptoms because she "has gone many times and the ER MD tells her the same thing." (*Id.*) Petitioner's primary care physician, Dr. Tran, returned her call the following day and informed her that the symptoms were likely normal and caused by anxiety. (*Id.* at 1334.) On September 5, 2014, petitioner had a telephone encounter with her

dermatologist. (*Id.* at 1339.) It was noted that petitioner "has many concerns, seems anxious." (*Id.* at 1339-40.) Her dermatologist noted, "[P]atient 'allergic' to doxy. . . . Otherwise, considered having patient apply topical sulfur sulfacetamide cleanser but patient allergic to sulfa." (*Id.* at 1340.)

On September 18, 2014, petitioner presented to the emergency department with complaints of unprovoked episode of palpitations, shortness of breath, and dizziness that lasted 6-7 seconds. (Ex. 2, p. 1349.) She reported that she was taking atenolol,[10] but she discontinued the prescription because it made her feel "weak." (*Id.*) A chest x-ray again showed no acute cardiopulmonary process. (*Id.* at 1353, 1359.) Petitioner was diagnosed with palpitations and discharged home. (*Id.* at 1353.) The next day, on September 19, 2014, petitioner called her primary care physician to report continued weakness, fatigue, lightheadedness, and shortness of breath, but no further palpitations. (*Id.* at 1393-94.) She explained that her episodes were increasing in frequency and length, though the episodes were still under a minute long. (*Id.*) Dr. Tran noted petitioner's normal workup before prescribing a low dose of Coreg.[11] (*Id.* at 1397.) She further noted that petitioner claimed taking Atenalol "caused [her heart rate] to go down too much." (*Id.*)

Petitioner presented for a routine exam with Dr. Fletcher on October 6, 2014. (Ex. 2, pp. 1408-09.) She complained of "her usual intermittent pelvic and abdominal pains," which she attributed to her fibromyalgia. She further reported weight gain and abdominal bloating since her ablation in May of 2014. (*Id.*) Dr. Fletcher assessed petitioner's abdominal bloating as likely due to weight gain. (*Id.* at 1409.) On October 9, 2014, petitioner had a telephone encounter with Dr. Tran, during which she complained of "pain all over her body with spasms and fluttering of muscles as well as pain in the ball of the feet, worse in the morning, in the last 1-2 weeks." (*Id.* at 1432.) Petitioner's symptoms were attributed to her fibromyalgia and elevated stress. (*Id.*)

On October 13, 2014, petitioner presented for a regular checkup with Dr. Tran. (Ex. 2, pp. 1439-40.) Petitioner reported that she discontinued Coreg because "it caused more lightheadedness and headache." (*Id.* at 1440.) Dr. Tran reiterated petitioner's complaints of fatigue, dizziness, and palpitations since the ablation, but questioned whether petitioner's reported symptoms were the result of anxiety. (*Id.* at 1440-42.) Petitioner returned to Dr. Tran on January 10, 2015, with complaints of pain in the balls of her feet when walking. (*Id.* at 1566-67.) She was diagnosed with bilateral metatarsalgia. (*Id.* at 1568.) During a telephone encounter with Dr. Tran on March 13, 2015, petitioner reported a four-day history of "heaviness" in the head and lightheadedness, as well as intermittent mid back pain and GERD for a few days. (Ex.

[10] Atenolol is an orally or intravenously administered treatment for hypertension, myocardial infarction, and cardiac arrhythmias. *Atenolol*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=4665 (last visited June 27, 2024).

[11] Coreg is another orally administered treatment for hypertension. *Coreg*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=11137 (last visited June 27, 2024); *Carvedilol*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=8176 (last visited June 27, 2024).

2, p. 1608.) Dr. Tran assessed petitioner's headache as likely due to allergies and suggested treating with an over-the-counter allergy medication. (*Id.*)

On January 15, 2015, petitioner's husband sent a message on petitioner's behalf to Dr. Tran with complaints of elevated blood pressure, dizziness, weakness, pain (all over her body but especially on her right side), shaking, and confusion. (Ex. 2, p. 1580.) He stated that petitioner refused to go to the emergency department "due to her bad experience in the past." That same day, petitioner had a telephone encounter with Dr. Tran. (*Id.*) Dr. Tran noted that petitioner "[h]as been filing a grievance against the ER yesterday; felt anxious and then this happened. Feels better today; just a little tired and some generalized weakness. . . . Likely anxiety attack." (*Id.* at 1580-81.) Dr. Tran advised treatment with rest, stress reduction, and Atvian as needed. (*Id.* at 1581.)

Petitioner sent a message to Dr. Fletcher on April 29, 2015, with complaints of memory loss that had been persistent for several months. (Ex. 2, p. 1626.) She explained that she was no longer taking any of her prescribed medications, with the exception of an estrogen cream, due to her "sensitivity to drugs." Citing a commercial that warned of the cream's potential side effects, which included abdominal pain and memory loss, petitioner was concerned that her memory loss could be a reaction to continued use of the estrogen cream. Dr. Fletcher reassured petitioner that the cream was unlikely to cause memory loss or abdominal pain and explained that topical application results in minimal absorption of the active medication into the bloodstream. (*Id.*)

In a telephone encounter on July 9, 2015, petitioner reported that her palpitations, body pain, and memory loss was progressing such that her activities of daily living were now affected. (Ex. 2, p. 1653.) Petitioner presented to Dr. Tran on July 13, 2015, with complaints of memory loss and itchy rash. (*Id.* at 1662.) Dr. Tran noted petitioner's normal neurologic exam and assessed petitioner with a mild cognitive impairment that was likely due to a mood problem. (*Id.* at 1662-63.) A CT scan of petitioner's head and brain again revealed no acute intracranial pathology. (*Id.* at 1684-90.)

b. Post-vaccination medical records

Petitioner received the subject flu vaccination on October 10, 2015. (Ex. 2, p. 1693; Ex. 13.)

One day later, in a telephone encounter on October 11, 2015, petitioner reported "new onset of dizziness and headache" since her flu vaccination. (Ex. 2, p. 1696.) She further complained of generalized weakness and impaired vision. (*Id.*) Petitioner was diagnosed with dizziness and headache, and it was noted that her symptoms could be a "[p]ossible side effect from her flu shot." (*Id.* at 1699.) She declined to go to an after-hours clinic and was advised to treat with hydration and rest. (*Id.*)

On October 13, 2015, petitioner had a telephone encounter with Dr. Tran, in which she reported dizziness, weakness, and headache since her flu vaccination. (Ex. 2, p. 1705.) She further reported experiencing a sore throat following her vaccination that eventually resolved. Dr. Tran's assessment was weakness, but she questioned whether petitioner's symptoms were a reaction to the flu vaccine or a viral syndrome. Noting that petitioner was feeling "somewhat better," Dr. Tran recommended continued treatment with hydration and rest. (*Id.*) On October 28, 2015, petitioner called to make an appointment with Dr. Tran because she was still feeling lightheaded and weak. (*Id.* at 1723.) She attributed her symptoms to her October 10, 2015 flu vaccination. She also reported a problem with her left fifth toe. (*Id.*)

Petitioner had another telephone encounter with Dr. Tran on October 29, 2015, in which she complained of intermittent weakness and dizziness since her flu vaccination. (Ex. 2, p. 1733.) Dr. Tran noted that petitioner "also has this with most meds in the past" and that she appeared to be improving. Dr. Tran diagnosed petitioner with fatigue and noted that "this is a chronic condition for this patient but she did say it got worse after her flu vaccine." (*Id.*) Petitioner further reported that she hit her left fifth toe on a table five days earlier, causing some swelling, which Dr. Tran assessed to be a sprain. (*Id.* at 1733-34.) A day later, on October 30, 2015, petitioner presented for a well-woman exam with Dr. Fletcher. (Ex. 2, p. 1737.) She reported a flare of her fibromyalgia symptoms and continued weakness following a "reaction to flu vaccine earlier this month." (*Id.*)

On November 3, 2015, petitioner sent a message to her primary care physician, providing an update on her "allergic reaction" to the flu vaccine. (Ex. 2, p. 1762.) Although she was feeling "a lot better than the first week," she reported that she was "still suffering from weakness, dizziness, headaches, intermittent palpitations, fatigue and body pains," and she was not yet "back to baseline." Dr. Tran suggested that petitioner try taking Relafen[12] for her pain and inflammation. She ordered lab tests to check for an infection or electrolytes problem. (*Id.*)

The next day, on November 4, 2015, petitioner sent another message to her primary care physician. (Ex. 2, p. 1777.) She reported that she had been taking Relafen without improvement in her pain. She further reported that she was experiencing pain at the base of her fingers that sometimes radiated to her wrists, which she suspected to be arthritis. She indicated that the symptoms were worse in her left hand and that her toes were sometimes affected. She also described intermittent "shooting pains" in her ankles, arms, shoulder joints, and back. (*Id.*)

Petitioner sent yet another message to her primary care physician on November 16, 2015. (Ex. 2, p. 1803.) She reported that her weakness, dizziness, and headaches

[12] Relafen is an orally administered nonsteroidal anti-inflammatory drug that is used in treatment of osteoarthritis and rheumatoid arthritis. *Relafen*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=43268 (last visited July 1, 2024); *Nabumetone*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=33049 (last visited July 1, 2024).

had improved, but she was still not back to normal or fully functional. She described feeling nauseous, fatigued, confused, clumsy, off-balance, and as if her head was "big and swollen." She reported "shaking" of her bilateral thumbs, which was more pronounced in the left thumb, since the ablation; however, she described how the symptom had gotten worse since the flu vaccination. She also described weakness in her hands and jitters in her teeth and lip. Finally, she reported that her memory issues had progressed, but she had "not started on the dementia medication due to [her] sensitivity to meds." Dr. Tran responded that petitioner's nonspecific symptoms and normal lab results indicated that petitioner's symptoms could be psychosomatic. Dr. Tran suggested that petitioner see a therapist. (*Id.*) Petitioner replied, "It's so unfortunate that I truly am suffering from symptoms that started and are still persisting after the flu vaccine," and requested a second opinion. (*Id.* at 1807.)

On December 10, 2015, petitioner called her primary care physician with reports of progressing dizziness, lightheadedness, and syncope since her flu vaccination. (Ex. 2, p. 1828.) In a telephone encounter the following day, petitioner further reported that her balance was off and "drifted" left and that she had gotten lost while driving home. (*Id.* at 1837.) Petitioner's differential diagnosis was ongoing dizziness, but she was referred to a neurologist for an evaluation for dementia. (*Id.* at 1839.)

Petitioner presented to Dr. Tran on December 30, 2015, with complaints of "many nonspecific symptoms x a few months," which she attributed to her flu vaccination. (Ex. 2, pp. 1888-89.) She described weakness, shakiness, memory issues, and palpitations. (*Id.* at 1889.) Dr. Tran noted that petitioner also had unfounded complaints of palpitations following her ablation and that petitioner declined to treat with Atenolol. (*Id.*) Dr. Tran's assessment was somatoform disorder, given petitioner's normal workup. (*Id.* at 1889-90.) She advised that petitioner treat with meditation, mindfulness exercises, and stress reduction. (*Id.* at 1890.)

On January 12, 2016, petitioner sent a message to her primary care provider, requesting a referral to a neurologist for evaluation of her ongoing weakness, irregular heart rate, dizziness, blurry vision, and tingling in her fingers and toes. (Ex. 2, p. 1920.) Petitioner also questioned whether a GBS panel had been ordered in the course of her treatment. (*Id.*) On January 12, 2016, petitioner presented for a consultation with neurologist Dr. Suzanne Koopmans. (*Id.* at 1924-25.) Dr. Koopmans briefly described petitioner's medical history. She noted that petitioner experienced numbness, dysphagia, vertigo, and falls in 2006 and was initially thought to have suffered a stroke. (*Id.* at 1925.) It was eventually determined that petitioner had a somatoform disorder. Dr. Koopmans then described petitioner's course since her flu vaccination:

> Received flu shot on 10/10/2015. Onset of symptoms was same day, a few hours later. Felt a bad headache. Then weakness, nausea, very dizzy. She stayed in bed. She said she couldn't even put her head up. Since then has had bad pains in legs and feet. Intermittent (not all the time) numbness in legs. Sometimes has pain and numbness in limbs and shoulder. Also c/o hands shaking/tremoring. This is when she is tired or cooking. At times

she drops things. Sometimes swallowing is hard as well. Also occasional slurred speech.

Since her cardiac ablation, still has palpitations from time to time.

At times has urinary urgency . . . . Feels so weak. Also c/o issues with memory. She thinks since the shot the memory is worse.

(*Id.*) Dr. Koopmans reviewed petitioner's most recent brain MRI and found only scattered white matter ischemic changes, and petitioner's neurologic exam was normal. (*Id.* at 1927.) She did not find any signs of dementia and reassured petitioner "that the flu shot did not cause any of her symptoms." (*Id.*)

Petitioner sent a message to her primary care physician in early February of 2016, complaining of progressing memory issues and continued pain, tingling, weakness, and numbness. (Ex. 2, p. 1967.) She described how her symptoms were intermittent but aggravated by exhaustion. She also reported continued palpitations. (*Id.*)

On February 10, 2016, petitioner completed a Vaccine Adverse Event Reporting System ("VAERS") report, alleging that she experienced an adverse reaction to the flu vaccine approximately two hours post-vaccination. (Ex. 9, p. 4.) She reported headache, dizziness, nausea, weakness, palpitations, and pain throughout her body, including her back and bilateral extremities. As pre-existing conditions, petitioner listed hypertension, hyperlipidemia, mild neurocognitive disorder, fibromyalgia, GERD, osteoporosis, and "high sensitivity + allergies to medications." (*Id.*) On a separate sheet of paper, petitioner listed 25 medications "with adverse reactions." (*Id.* at 5.)

Petitioner saw primary care physician, Dr. Winnie Gandingco, on February 19, 2016, with complaints of weakness, "pins and needles" sensation in her bilateral extremities, and generalized myalgia. (Ex. 2, pp. 1990-92.) In a follow up message to Dr. Gandingco, petitioner reported excruciating pain in her hands, fingers, and arms; tingling in her fingers and arms; and some swelling and redness in the palms of her bilateral hands, but especially in her right palm. (*Id.* at 2005.) Dr. Gandingco responded that petitioner's workup was normal and "there is still no explanation for [her] symptoms except for the mildly elevated eosinophils which is a marker for allergies." She suggested treatment with an over-the-counter allergy medication. (*Id.*) The next day, petitioner sent another message to Dr. Gandingco, reporting additional symptoms. (*Id.* at 2028.) She described tingling and numbness in her face, which resolved after a couple days, and pain that caused weakness, tingling, and aches. She also stated that her chest felt "weird." (*Id.*)

On March 1, 2016, petitioner reported a three-month history of "[d]isabling axial pain," and underwent an MRI of her lumbar spine that was unremarkable. (Ex. 2, pp. 2037-41, 2045-51.) Petitioner's differential diagnosis was myofascial pain syndrome, which Dr. Gandingco explained is the same as fibromyalgia. (*Id.* at 2045-46, 2136.)

Petitioner indicated her disagreement with her diagnosis. (*Id.* at 2045.) She described her condition as including persistent and unbearable pain, tingling, pricking, shooting, deep aches, and weakness throughout her body. (*Id.* at 2047.) She also reported memory issues, fatigue, irregular heart rate, and coldness in her hands and feet. She explained that her symptoms were worse at night and that her pain was aggravated by touch. (*Id.*)

In a telephone encounter on March 4, 2016, petitioner complained of pain, numbness, and tingling since her flu vaccination in October of 2015. (Ex. 2, p. 2062.) She reported a one-day onset of pain following her vaccination, but she explained that she ignored her symptoms because she believed they were associated with her fibromyalgia. She described worsening numbness and tingling in her bilateral extremities, torso, and spine. (*Id.*) On March 16, 2016, petitioner sent a message to Dr. Gandingco, complaining of swollen gums and rashes around her mouth. (*Id.* at 2090.) Petitioner also explained, "I've had so [many] problems in my body since after the flu shot in October 2016. . . . I truly believe that the vaccine had adverse effects on my body." She requested that the flu vaccine be included in the allergy list on file. (*Id.*) Later that month, on March 29, 2016, petitioner sent another message to Dr. Gandingco, requesting that the recent diagnoses of peripheral neuropathy, chronic fatigue syndrome, fibromyalgia, myofascial pain, and mild neurocognitive disorder due to multiple etiologies be added to her file. (*Id.* at 2136.) Dr. Gandingco added peripheral neuropathy, chronic fatigue syndrome, and fibromyalgia to petitioner's chart, but she explained that she did not include myofascial pain due to its similarity with fibromyalgia or mild neurocognitive disorder because it "is a vague diagnosis and does not really mean anything." (*Id.*)

On April 16, 2016, petitioner sent another message to Dr. Gandingco, describing stabbing pains in her upper back and lungs, which began in the early morning hours on April 15, 2016, and continued throughout the day. (Ex. 2, p. 2202.) In the afternoon, on April 15, 2016, petitioner noticed swelling and greyish tint in the three middle fingers of both hands. She noticed the greyish tint in her lips as well. She further described an increase in fatigue and weakness as a result of the aggravated pain. By the evening, petitioner was experiencing upper chest heaviness and tightness, prompting her to go to the emergency department. (*Id.*) Petitioner underwent a deep venous sonogram of her bilateral lower extremities, which was unremarkable. (*Id.* at 2239-40.)

Petitioner sent another message to Dr. Gandingco on May 16, 2016, this time reporting constant numbness; tingling and deep aching in fingers, hands, toes, and feet; and fatigue and weakness in the bilateral extremities, although the latter two symptoms had been generally less intense. (Ex. 2, p. 2295.) She further reported improvement in frequency of "shooting, pinching and prickling pains." However, she explained that these symptoms were "disabling" and interfering with her activities of daily living. (*Id.*)

The next day, on May 17, 2016, petitioner presented to Dr. Irina Williams for evaluation of chronic pain that she attributed to her flu vaccination. (Ex. 2, pp. 2303-07.) Dr. Williams noted that petitioner suffered "chronic pain involving all extremities

with some [on the] trunk. Non-specific. Fibromyalgia? Myofascial pain? Also has features of chronic fatigue." (*Id.* at 2303.) Petitioner reported generalized body pain that was worse over the bilateral arms, hands, and feet. (*Id.* at 2303-04.) She described the pain as "sharp" and "burning," and she reported that it was associated with widespread paresthesia. (*Id.*)

On July 6, 2016, petitioner sent a message to Dr. Gandingco, reporting persistent weakness, fatigue, and exhaustion. (Ex. 4, p. 78.) These symptoms were both aggravated by and interfering with her activities of daily living. She described how, "[e]ven with modifications on the stretches from the Chronic Pain Class, it still caused prickling, tingling and stabbing pains which got worse overnight. It rendered me very weak, fatigued, exhausted and with bad aching pains today . . . . I can't help but take my pain medication which I try to avoid . . . ." (*Id.*) Later that month, on July 14, 2016, petitioner sent a message to Dr. Williams, providing an update on her condition. (*Id.* at 95.) She reported that she was "still in a lot of pain (mostly deep aches which are constant; intermittent shooting, pricking, tingling and numbness on my fingers, hands, toes, feet and extremities on both sides . . . . Weakness, exhaustion and fatigue are still constant . . . ." She again reported that she modified the chronic pain class exercises, but the exercises caused tingling and shooting pains in her fingers, toes, feet, extremities, and back. (*Id.*)

On August 15, 2015, petitioner sent another message to Dr. Gandingco, providing the following update:

> It has been over 10 months since the flu vaccination on October 10, 2015. Weakness is still constant daily . . . , with tingling, pricking and aching pains . . . still persisting. It's been a struggle inching back to more house and social activities. All of these with extreme difficulties, pains, weakness, anguish, frustration and depression. It shoots my symptoms up to the roof . . . . And it takes days, sometimes weeks to get better. I am not even back to my regular activities yet.

(Ex. 4, p. 202.) Later that same day, petitioner presented to the emergency department with complaints of syncope. (*Id.* at 164; Ex. 30, p. 8.) She reported that she woke up with a headache in the front of her head. (Ex. 4, p. 164.) Then, in the early afternoon, petitioner had an episode of syncope. She described walking upstairs, laying down in bed with her feet elevated, and fainting upon standing up from her prone position. She reported that she landed face down on her bed without injury, but she could not recall how long the episode lasted. Since then, she continued to experience headache and tingling in her extremities, though she reported that she had been experiencing common headaches lately. She further reported experiencing intermittent palpitations for the past few weeks, though it was noted that there had been no objective evidence of supraventricular tachycardia since her ablation in May of 2014. Finally, petitioner reported that she "[h]as had numbness and tingling in her hands and feet since Oct 2015. She associates this with her influenza shot. Sitting on the toilet seems to make it worse. Starts in the tips of her toes, then in her finger tips." (*Id.*) Petitioner's physical

and neurologic exams were normal, and her lab and EKG results were unremarkable. (*Id.* at 167-69.) She was discharged home with a diagnosis of syncope. (*Id.* at 169.) On August 18, 2016, petitioner had a telephone encounter with behavior medicine specialist Dr. Bradley Kuper, who diagnosed her with pain disorder associated with medical and psychological disorders. (*Id.* at 221.)

On August 22, 2016, petitioner presented to Dr. Gandingco for a routine follow up appointment. (Ex. 4, pp. 231-32.) She reported continued muscle weakness, numbness or tingling sensation, and pain in the hands and feet. (*Id.* at 231.) Dr. Gandingco noted, "When asked to give details of the pain, patient becomes very vague. When asked to localize the pain she will point to multiple areas but unable to give details and then moved back to getting more testing done . . . Patient feels that her symptoms are related to the flu shot[.]" (*Id.*) Dr. Gandingco further noted that "most of [petitioner's] symptoms pre-date the flu vaccine including her fatigue, numbness and weakness." (*Id.* at 232.) Petitioner was diagnosed with persistent somatic symptom disorder. (*Id.* at 233.)

Petitioner presented to neurologist Dr. Amir Sabouri on October 31, 2016, for an evaluation of pain. (Ex. 5, p. 29.) She described how she developed weakness, generalized pain, and an upset stomach within "26 hours" of her flu vaccination. She complained of pain and numbness in her extremities, as well as generalized fatigue. However, she denied weakness in the extremities and headache. (*Id.*) Dr. Sabouri noted that petitioner presented "with a constellation of findings suggestive of idiopathic small fiber neuropathy (pain in lower extremities, worse at night, numbness, gradient sensory loss to pinprick and temperature) and otherwise unremarkable neurological examination." (*Id.* at 31.) He suggested treatment with a neuropathic pain medication, but petitioner was hesitant due to her sensitivity to medications. (*Id.*) When petitioner inquired into whether the flu vaccine could have triggered the small fiber neuropathy, Dr. Sabouri indicated determining whether the vaccine could have caused small fiber neuropathy would not change the treatment or prognosis of her condition. (*Id.* at 32.)

Petitioner's next encounter was for an evaluation of peripheral neuropathy with neurologist Dr. Ryan Armour on April 18, 2017. (Ex. 6, p. 5.) Petitioner reported

> that her symptoms started around 2006. She reports that symptoms started with decreased coordination and a feeling of heaviness in her legs with some confusion. She was admitted to the hospital and had a workup that was negative for stroke. She was diagnosed with somatiform [sic] disorder.
>
> She reports that she felt totally normal between 2006 and 2015. She got a flu vaccine in October 2015. She says that in the first few hours after the flu vaccine she got dizzy, nauseated and felt a headache with severe generalized muscle weakness that prevented her from walking unassisted. She says that she called her doctor the following day and was told that she was having a severe allergic reaction to the flu shot.

> Since the episode with the flu shot she reports that she has had the following problems: . . . She reports that she has chronic severe weakness and fatigue in the extremities. Walking short distances is difficult for her. Walking just across a building makes her feel like she has run a marathon. . . . She reports that she has frequent urination up to 9 times per day. . . . Chest discomfort with palpitations, but other times she feels like her heart is "slow and weak, like my heart is dying." She feels weak when this occurs. . . . She reports that she has labile blood pressure, ranging from 100/60, which she described as "low," up to 170/90. . . . Low back pain and bilateral leg pain, feeling like electricity and tingling along with a deep ache in the back that shoots into the legs. Initially this was intermittent but now is constant. . . . Numbness in the toes that has progressed to include the entire lower limb on both sides as well as the fingers, hands, arms, shoulders and low back.
>
> The patient reports that she saw a neurologist in 2016 and was told she was normal and there was no neurological problem present. She says that she got another opinion from a neuromuscular specialist. She did an EMG/NCS and was told that she did not have any problem with the large fibers. She did not have any testing for small fiber polyneuropathy but she received a diagnosis based on clinical history and examination.

(*Id.* at 5-6.) Dr. Armour noted that petitioner presented for a neurologic opinion regarding chronic fatigue, numbness, and weakness of the extremities with a variety of other non-neurological symptoms. (*Id.* at 11.) Finding that there was no objective evidence of GBS or small fiber polyneuropathy, he determined that petitioner most likely suffered from a combination of somatoform disorder and fibromyalgia. (*Id.* at 11-12.) He noted that petitioner was "resistant to try any treatment due to concern about side effects." (*Id.* at 12.)

Petitioner returned to Dr. Armour on May 30, 2017, for a follow up. (Ex. 6, p. 36-45.) She reported continued fatigue, weakness, exhaustion, and pain in her extremities and low back, as well as difficulty with balance and coordination. (*Id.* at 36.) She also continued to report that the flu vaccine exacerbated all of her symptoms. Dr. Armour listed several treatments that petitioner tried and explained why each treatment was discontinued. (*Id.*) He noted that all testing for neurological disorders had been normal and stated, "I still believe symptoms are due to a combi[n]ation of somatization and fibromyalgia." (*Id.* at 44.) Petitioner denied all offered interventions. (*Id.*)

On January 30, 2018, petitioner presented to Dr. David Lee with complaints of "all over pain." (Ex. 7, p. 19.) She reported pain and tingling across her abdomen, shooting pain in her feet and back, memory issues, "'fireworks type' pain" in her finger and hands, pins and needles sensation in her eyelids, fatigue, and weakness. (*Id.*) Petitioner returned to Dr. Armour on May 8, 2018, for an evaluation of generalized pain and fatigue. (*Id.* at 13.) Dr. Armour noted, "Diagnosis is likely fibromyalgia. Somatoform disorder is on the differential as well. Sensation remains decreased in the

distal extremities. It is unclear if there is a small fiber polyneuropathy contributing to her symptoms. Patient would like a definitive diagnosis." (*Id.* at 17.) He suggested that a skin biopsy or other quantitative sensory testing could confirm diagnosis, but such testing was not covered by petitioner's insurance. (*Id.*)

On October 3, 2018, petitioner presented to neuromuscular disease and EMG specialist and neurologist Dr. Jonathan Katz for "[m]ultiple complaints stemming from a vaccine." (Ex. 15, p. 9.) Petitioner described onset of headache, inability to hold her head up, nauseousness, and dizziness the day after her flu vaccination. When she called her primary care physician, she was told that she had a severe allergic reaction to the vaccine that would soon improve. However, she reported persistent weakness and shooting pain in her back, arms, and legs that she attributed to her history of fibromyalgia. The tingling progressed to her toes and hands. She eventually experienced "an 'explosion of pain' including sharp pains in the toes that made her have to walk with the toes bent upwards" and resulted in limited gait, and she cannot move some of the toes on her left foot. (*Id.*) Petitioner told Dr. Katz that she was bedridden after a mild stroke in 2001 and "had one more mild period of being bedridden last year, when she got the flu and it felt like this problem was starting again." (*Id.* at 10-11.) Despite seeing several doctors and undergoing various testing, but no neurological problem was identified. (*Id.*) Dr. Katz noted,

> These are interesting complaints but I am of the belief that she is physically okay with respect to the nervous system. Took a fairly detailed history and spent time explaining how she is doing to her, and tried to tie this in with some of her other symptoms.
>
> . . . Fibromyalgia from her vaccine. I do think that independent of her concerns and needing to reassure that she does not have some sort of severe illness or degeneration, there is a basic issue of why she has so much pain, and I think this fits best with her history.

(*Id.* at 12.) Petitioner returned to Dr. Lee on October 16, 2018, for follow up appointment. (Ex. 16, p. 50.) She reported that the intensity of pain fluctuated and remained "electric and sharp" in character. She described numbness in her toes. (*Id.*) It was noted that petitioner "continues to be adamant against any medications at this point." (*Id.* at 51.)

Petitioner next saw Dr. Lee on February 15, 2019, for another follow up appointment. (Ex. 16, p. 56.) Petitioner reported that she was treating with over-the-counter supplements and declined additional medications, but she was still experiencing fatigue throughout the day that was aggravated by exertion. Although she continued to experience pain throughout her body, she reported that her symptoms were "somewhat improved from before." (*Id.*) Petitioner returned to Dr. Lee on June 6, 2019, with complaints of sluggishness and lightheadedness. (*Id.* at 41.) She described numbness affecting both sides of her body, nauseousness, sluggishness, and tingling in her toes, feet, and fingertips. (*Id.*)

On July 19, 2019, petitioner saw nurse practitioner Julie Amoruso with complaints of a three-day history of shooting pain in her bilateral wrists and grip weakness. (Ex. 16, p. 35.) She described anxiety regarding a possible right lateral wrist fracture due to digging motion "and this anxiety has made her weak/fatigued/chronic pain worse." (*Id.*) She was given wrist splints and diagnosed with chronic fatigue syndrome with fibromyalgia. (*Id.* at 36.) On August 21, 2019, petitioner saw Dr. Lee with complaints of weakness in all extremities; pain in her toes, feet, and upper limbs; and numbness. (*Id.* at 19.) Somatoform disorder is listed in her ongoing problem list for this appointment. (*Id.*) Petitioner returned to Dr. Lee on September 10, 2019. (*Id.* at 30-31.) Dr. Lee noted, "Continued paresthesias per patient and aggravated more so on left side of face again . . . . She continues to defer on additional medications for this." (*Id.* at 31.)

Petitioner presented for a skin biopsy for evaluation of generalized tingling and painful paresthesia on October 18, 2019. (Ex. 56, pp. 13-14.) The results revealed no evidence of small fiber neuropathy. (*Id.* at 13.) On December 13, 2019, petitioner returned to Dr. Katz with complaints of numbness, difficulty breathing, and palpitations. (Ex. 15, p. 13.) She further reported brain and memory issues, red spots on her fingers, and vision issues. (*Id.*) Dr. Katz noted, "Multiple complaints, but mainly numbness in the setting of a normal exam. This is similar to when I last saw her. I still suspect this is an undifferentiated somatiform [sic] disorder." (*Id.* at 16.)

Petitioner's next encounter was a follow up appointment with Dr. Armour on February 12, 2020. (Ex. 56, p. 7.) She reported burning pain, numbness, and tingling in her hands and feet, as well as intermittent neck and low back pain and occasional tingling on the left side of her head. (*Id.*) She further reported tremors in her hands, though there was no evidence of tremor on exam. (*Id.* at 7, 11.) Dr. Armour listed the various treatments that petitioner tried and why she discontinued them. (*Id.* at 7-8, 11.) He noted that petitioner had been evaluated by three other neurologists with no clear neurological diagnosis and that, on examination, petitioner's memory and speech were normal. (*Id.* at 8-11.) He determined that petitioner's likely diagnosis was fibromyalgia, but somatoform disorder was on the differential as well, and that petitioner had either not tolerated or refused to try medical management of her fibromyalgia. (*Id.* at 11.)

On March 24, 2020, petitioner had a virtual encounter with Dr. Lee, during which she described an episode of "a bit of blacking out," a feeling of fullness in her head, sweating, palpitations, and mild shortness of breath. (Ex. 57, p. 27.) Her symptoms resolved after resting and elevating her legs, but her blood pressure was still elevated. (*Id.*) Dr. Lee's assessment was near syncope. (*Id.* at 28.) On May 15, 2020, petitioner returned to Dr. Lee with complaints of lightheadedness upon waking up in the morning and fluctuating blood pressure. (*Id.* at 7.) She further reported that her sense of taste diminished for a week before slowly resolving. She also experienced some upper back and abdominal pain, tightness, and tremor in her left index finger. (*Id.*) Dr. Lee's assessment was chronic fatigue syndrome with fibromyalgia and tremor, despite normal exam. (*Id.* at 8.)

Petitioner had another virtual encounter with Dr. Lee on October 12, 2020. (Ex. 57, p. 38.) She reported improvement in her fatigue and "less pain in general from fibromyalgia but somewhat aggravated if she does too much or with increased stress." However, she reported ongoing numbness in her fingers. Somatoform disorder was listed on her ongoing problem list. (*Id.*) Regarding petitioner's chronic fatigue syndrome with fibromyalgia, Dr. Lee noted: "Slowly improving per patient." (*Id.* at 39.) He recommended incremental increases in endurance activities. Regarding her tremor, Dr. Lee noted that petitioner deferred further medical treatment. (*Id.*) Petitioner returned to Dr. Lee on November 16, 2020, complaining of pain and numbness in her left fingers. (*Id.* at 12.) She reported that her symptoms, including left hand and arm tremors, were aggravated by exertion. (*Id.*) Dr. Lee's assessment was tremor and stable chronic fatigue syndrome with fibromyalgia. (*Id.* at 13.)

On December 31, 2020, petitioner presented for a virtual appointment with Dr. Lee. (Ex. 57, p. 42.) She reported flu-like symptoms, fatigue, "slight breathing tightness," and pain in her back and sides. Somatoform disorder remained on petitioner's ongoing problem list. (*Id.*) Dr. Lee diagnosed her with flu syndrome. (*Id.* at 43.) As for petitioner's chronic fatigue syndrome with fibromyalgia, Dr. Lee stressed that petitioner rest and not overexert herself. (*Id.*) Petitioner returned for another virtual appointment with Dr. Lee on January 13, 2021. (*Id.* at 51.) She reported an overall improvement in her blood pressure and that her energy level was almost back to baseline. (*Id.*) Dr. Lee noted that petitioner's anxiety was stable, and her chronic fatigue syndrome with fibromyalgia was "[s]lowly improving per patient to prior baseline." (*Id.* at 52.) Petitioner again deferred medical treatment of her tremor. (*Id.*)

On May 14, 2021, petitioner presented for another virtual appointment with Dr. Lee. (Ex. 57, p. 17.) Petitioner reported "ongoing tremoring and weakness at times in both hands, left > right," as well as numbness and throbbing in the left hand. Her physical examination revealed a very mild resting tremor in the left hand. Petitioner's differential diagnosis was essential tremor, coupled with somatic factors. (*Id.*) Petitioner also reported short-term memory issues, but Dr. Lee deferred evaluation until further testing was complete. (*Id.* at 18.)

Petitioner presented for an in-person appointment with Dr. Lee on June 21, 2021, with complaints of continued pain in left fingers with numbness, tightness, and burning. (Ex. 57, p. 55.) She was unaware of any specific activities or positioning that could be provoking her symptoms. Although she was not treating with medication, she tried supplements and reported some improvement in her symptoms. Somatoform disorder continued to be included on petitioner's ongoing problem list. (*Id.*) Dr. Lee's assessment included carpal tunnel syndrome and tremor. (*Id.* at 56.)

On December 3, 2021, petitioner presented for a Medicare wellness exam with Dr. Lee. (Ex. 57, p. 21.) Due to continued imbalance, weakness, and lack of endurance, petitioner reported needing the support of a cane to ambulate at home and a wheelchair when going out for extended periods. She reported stress, and

somatoform disorder continued to be listed as an ongoing problem. (*Id.*) Dr. Lee assessed petitioner with chronic fatigue syndrome with fibromyalgia and tremor. (*Id.* at 22.) He noted that petitioner was resistant to trying medication. (*Id.*)

During her next encounter with Dr. Lee on March 4, 2022, petitioner reported a one-day onset of headache along the back of the neck and head, resulting in exhaustion and lightheadedness. (Ex. 57, p. 34.) She described feeling "a bit of pressure swelling in her head," intermittent stress, and episodes of misspeaking. (*Id.*) Dr. Lee's assessment included chronic fatigue syndrome with fibromyalgia and tension headache. (*Id.* at 35.) He noted that her symptoms were likely exacerbated by her headache and recent increase in activities. (*Id.*) Somatoform disorder was again listed as an ongoing problem. (*Id.* at 34.) Petitioner returned to Dr. Lee on July 14, 2022, with reports of left rib pain that radiated to her back and was aggravated by certain movements. (*Id.* at 46.) Her pain was the likely result of trauma from "jamming her cane into [the] left chest area." She further reported feeling intermittent tightness across the base of her left ring and pinkie fingers and memory issues. (*Id.*) Dr. Lee's assessment included rib injury, trigger finger of the left hand, and anxiety that was likely contributing to her reported memory issues. (*Id.* at 47.) Somatoform disorder was again listed as an ongoing problem. (*Id.* at 46.)

On October 12, 2022, petitioner presented to Dr. Lee with reports of falling off the bed, landing on her back, and potentially losing consciousness. (Ex. 57, p. 60.) Dr. Lee's assessment included near syncope and chronic fatigue syndrome with fibromyalgia that was exacerbated by her recent fall. (*Id.* at 61.) Somatoform disorder continued to be included in petitioner's ongoing problem list. (*Id.*)

c. Petitioner's affidavit

In her affidavit, petitioner states that she began to experience severe headache, dizziness, nausea, weakness, and balance issues within a couple hours of receiving the flu vaccine on October 10, 2015. (Ex. 1, ¶¶ 3-4.) She reports that she was bedridden for the rest of the day and could only tolerate liquids due to her nausea. (*Id.* ¶ 5.) Upon waking up the next morning, petitioner describes feeling "shooting and deep aching pains" in her back, shoulders, and sides, as well as stiffness and numbness in her limbs, which made her feel weak and exhausted. (*Id.* ¶ 6.) She reports that she deferred going to the hospital, but her husband called Kaiser Permanente and the on-call physician suggested that petitioner may have suffered from a severe allergic reaction to the flu vaccine. (*Id.* ¶ 7.) Petitioner was told that her symptoms would resolve after a couple of days. (*Id.*)

Petitioner reports that she called her primary care physician, Dr. Tran, on October 13, 2015, and was advised that her symptoms could be "a possible reaction to the flu vaccine," and that her symptoms may continue for two months before eventually subsiding. (Ex. 1, ¶ 8.) Petitioner states that, at that point, she was hopeful that her pains were due to her pre-existing fibromyalgia. Despite not being asked about the specifics of her pain at that time, petitioner recalls that it was radiated up her arms and

legs and into her back. She did however report irregular heart rate and feeling as though she had a weak pulse. She claims that her fibromyalgia and irregular heart rate "were worse after the vaccination." (*Id.*)

Later that month, petitioner states that she called her primary care physician again with complaints of weakness, dizziness, and extreme fatigue. (Ex. 1, ¶ 9.) The following day, on October 30, 2015, petitioner presented for a woman annual exam and reported that she was experiencing what she believed to be a flare of fibromyalgia and that she had an adverse reaction to the flu vaccine. (*Id.* ¶ 10.) Thereafter, petitioner states that she continued to report pain in her fingers, wrists, toes, ankles, limbs, shoulders, back, mid-body, and spine, as well as tingling in her cheeks, numbness, drooling, and urinary issues. (*Id.* ¶ 11.) She also reported mood changes and less feeling in her palms and feet. (*Id.*)

Petitioner states that, at some point prior to January 2016, Dr. Tran informed her that it would be difficult to link her symptoms to the flu vaccination but, given petitioner's medical history and "high sensitivity to medications," it was possible that she suffered an allergic reaction to the flu vaccine. (Ex. 1, ¶ 12 (emphasis omitted).) Dr. Tran further informed her that her symptoms could last for a year or two and ordered lab tests, which were normal. (*Id.*) Petitioner describes how her symptoms prevented her from going on vacation with her family in January 2016 and notes that Dr. Tran provided a note detailing why her tachycardia warranted cancellation. (*Id.* ¶ 13.) During a neurology appointment that same month, petitioner reports that there was no evidence of neurological disorder, or any other injury caused by the flu vaccine, as her reflexes remained intact. (*Id.* ¶ 14.) However, petitioner states that her treating neurologist, Dr. Koopmans, did not credit her description of the events following her vaccination and "was not specific and thorough with the examination." (*Id.*)

On February 19, 2016, petitioner presented for an appointment with her new primary care physician, Dr. Gandingco, who reassured her that her symptoms "are real and not just a product of [her] mind." (Ex. 1, ¶ 15.) Dr. Gandingco diagnosed myalgia; however, petitioner states that Dr. Gandingco "was not specific with the evaluation and pain interview." Petitioner further notes that her lab tests showed elevated markers for allergies and that Dr. Gandingco indicated that medications and vaccines can trigger this elevation. (*Id.*)

Petitioner reports that Dr. Gandingco was more thorough in a subsequent examination. (Ex. 1, ¶ 16.) During this encounter, petitioner reported tingling, prickling, shooting, stabbing, and deep-aching pain throughout her body but especially in her three middle fingers and toes. (*Id.*) Dr. Gandingco diagnosed peripheral neuropathy, fibromyalgia, and chronic fatigue syndrome. (*Id.*) She explained that peripheral neuropathy has no known cause or treatment. (*Id.* ¶ 17.) Because Dr. Koopmans found no evidence of neurologic disorder, petitioner's referral for further testing was declined. (*Id.*) Dr. Gandingco reiterated Dr. Tran's suggestion that petitioner's symptoms could persist for one to two years and that it would be hard to prove that they were linked to her flu vaccination. (*Id.* ¶ 23.)

Petitioner states,

> I am very disappointed that when some doctors are unable to find or make a firm diagnosis, they could be quick at using Somatoform as a diagnosis. I was misdiagnosed with this when they were unable to catch my Tachycardia. It took months before this was caught in the ER, when my palpitation was exceeding 100 to over 200 per minute, lasting over 1 hour to more than 2 hrs.
>
> . . . I read my medical record and found that some doctors referred to and might have considered Somatoform. Sadly, I find it like a way of escape when there is no clarity or clear-cut symptoms and diagnosis.

(Ex. 1, ¶¶ 18-19.) She explains that she was originally diagnosed with somatoform disorder after suffering from a stroke for which there was no objective evidence. (*Id.* ¶ 20.) She states that some doctors reviewed her previous MRI results and determined that there was some evidence of stroke. She further indicates frustration because, despite uncertainty among treaters about her correct diagnosis, she has been denied insurance due to this prior stroke. (*Id.*)

During the first two months following vaccination, petitioner describes the following additional symptoms: frequent urination, difficulty controlling her urination, numbness, occasional and mild tingling of the cheeks, worsening memory issues, and a weaker immune system as evidenced by frequent rashes, swelling, coldness, paleness, and reduced sensation to touch and taste. (Ex. 1, ¶ 21.) She describes depression, crankiness, and anxiety that negatively affect her familial relationships. (*Id.* ¶ 22.) She notes that there is a "long list of medications that cause allergies and severe reactions documented on [her] medical file." (*Id.* ¶ 25.) Petitioner explains that patients with sensitivities are usually administered a "Flu Shot without Preservatives," but she received a "Regular Strength Flu Shot" or a "Flu Shot with Preservatives Added." (*Id.* ¶ 24.) She states that she usually receives the flu vaccine without preservatives and that she has never suffered an adverse reaction. (*Id.*)

Petitioner reports that she was denied a second opinion due to unavailability of neurologists to take her case. (Ex. 1, ¶ 26.) By December 2016, petitioner reports that she got the flu and experienced symptoms that were similar to those experienced after receiving the flu vaccine in October 2015. (*Id.* ¶ 27.) She describes weakness, fatigue, pain, dizziness, nausea, and frequent urination, as well as new onset of fever. Her fatigue, pain, and weakness were so severe that she was confined to her bed. She was eventually seen on December 23, 2016, for respiratory infection. (*Id.*)

Petitioner attended home physical therapy in the January and February of 2017. (Ex. 1, ¶ 28.) She reports that her physical therapist informed her that strenuous exercises would do more harm than good and suggested that her problems may be neurologic in nature. (*Id.*) At discharge, petitioner describes how her physical therapist

pushed her to walk up and down the stairs, intensifying her symptoms, and causing a loss in progress towards recovery. (*Id.* ¶ 29.) It was suggested that both her inability to ambulate on stairs and to maintain balance without falling backwards were signs of petitioner's weakness and poor balance. (*Id.* ¶¶ 30-31.)

Petitioner states that neuromuscular specialist, Dr. Armour, diagnosed her with chronic fatigue syndrome, paresthesia, and severe fibromyalgia, which could have been exacerbated by the flu vaccine. (Ex. 1, ¶ 34.) She explains that Dr. Armour believed that she also presented with symptoms consistent with small fiber neuropathy, although this differential diagnosis was never confirmed because her insurance denied coverage of testing. (*Id.* ¶ 35.) Petitioner underwent her first spinal tap in May 2017, "over a year after the vaccination," and the results showed an elevated total protein count. (*Id.* ¶ 36.)

In October 2018, petitioner presented to Dr. Jonathan Katz at Sutter Pacific Medical Group who agreed that the flu vaccine "gravely exacerbated" petitioner's fibromyalgia and fatigue. (Ex. 1, ¶ 37.) However, he explained that petitioner's symptoms belong to the broad family of fibromyalgia and their relationship to petitioner's flu vaccine was unclear, given that it had been nearly three years since the vaccination. (*Id.*) Petitioner reports that Dr. Katz's primary diagnosis was vaccination complication. (*Id.* ¶ 39.)

Despite some improvement, petitioner reports that her symptoms are persistent and disabling. (Ex. 1, ¶ 41.) She explains that, on top of aggravating her fibromyalgia, the flu vaccine caused pain that was different and more constant than the pain associated with her fibromyalgia. (*Id.* ¶¶ 42-43, 45.) She describes "pin prick pain (almost constant, intensity is like a roller coaster) radiating from toes up and down the legs (both sides) and fingers, hands, and arms," as well as "sharp and shooting pains in the same places." (*Id.* ¶ 44.) She further describes numbness in her legs, feet, and toes (especially her three little toes) on both sides. (*Id.*) Although she is able to ambulate short distances with support, petitioner explains that she still requires a wheelchair for long walks. (*Id.* ¶ 46.) She states, "I have never been back to my baseline before the Flu Shot. Weakness, fatigue and pains are still part of my daily living (4 to 10 on the pain scale)." (*Id.*) She reports that she still experiences "aggravations due to activities and for unknown reasons." (*Id.* ¶ 47.)

d. Affidavit of petitioner's husband, Arthur Valdez

Petitioner's husband, Arthur Valdez, submitted an affidavit on her behalf. (Ex. 10.) In his affidavit, Mr. Valdez states that he also received the flu vaccine on the morning of October 10, 2015, but by the afternoon, petitioner began complaining of extreme headache, dizziness, nausea, weakness, and imbalance. (*Id.* at 1.) He describes how she was unable to open her eyes, speak, or move due to the dizziness and nausea. By the next day, petitioner was suffering deep, shooting pains and aches throughout her body. Mr. Valdez explains that he was worried about her condition, but petitioner refused to go to the emergency room due to "[h]er previous traumatizing experience at Kaiser Emergency Room." He states that, although petitioner has

"serious susceptibility to medications," her reaction to the flu vaccine "was the worst and longest allergic reaction she ever had and is still having residual up to present." He explains, "I am a witness to this as she experienced danger from different medications before the Flu Shot. Unlike other people, her body reacts quicker to medications." He further states that petitioner "never got back to how she was before the administration of the Flu Shot." (*Id.*)

Mr. Valdez reiterates many of petitioner's assertions concerning the quality of her symptoms and the effect that they have had on her life. He describes "shooting pains, pin prick, tingling, burning and deep aches, fatigue, weakness, numbness and poor balance" throughout petitioner's body. (Ex. 10, p. 1.) He notes that she continues to tire easily, which limits her ability to ambulate and perform activities of daily living. (*Id.* at 1-2.) He explains that she eventually resorted to using an electric toothbrush, doing sponge baths, and sitting on a chair while performing personal hygiene activities. (*Id.* at 1.) She had trouble holding things, especially skinny objects like silverware, and experienced frequent urination. (*Id.* at 1-2.) Eventually, petitioner stopped driving due to the pain, numbness, fatigue, and weakness in her bilateral extremities. (*Id.* at 1.) Mr. Valdez reports that petitioner's skin was sensitive to the slightest touch, causing electric and burning pains, and that "[t]here were months of sleepless nights." (*Id.* at 2.)

Mr. Valdez states that petitioner's treaters associated her symptoms with her flu vaccination. (Ex. 10, p. 2.) He describes how, despite experiencing some improvements, petitioner still complains that her symptoms are aggravated by activity and "some unknown reasons." He notes that her symptoms prevent her from traveling, performing activities of daily living, and attending church, family gatherings, and holiday celebrations. He concludes that petitioner's condition "was never like this before the Flu Shot" and that she is still "far away from how she was before the Flu Shot." (*Id.*)

IV. Expert Summaries

a. Petitioner's expert, W. Curt LaFrance, Jr., M.D., M.P.H.[13]

Dr. LaFrance filed three reports in this case. (Exs. 17, 34, 45.) Dr. LaFrance notes that petitioner had a medical history inclusive of a number of issues, including back pain, lightheadedness, tachycardia, fibromyalgia, headaches, anxiety, and depression. (Ex. 17, p. 32.) He explains that she is a patient "who has a longstanding history of physical symptoms, who describes development and worsening of her symptoms after a 10/10/2015 Fluvirin injection." (*Id*.) However, he agrees that "[h]er workup does not reveal a medical or neurological etiology for her symptoms, and her

[13] Dr. LaFrance received his medical degree from the Medical College of Georgia before completing an internship in internal medicine, a residency in neurology and psychiatry, and a fellowship at Brown University School of Medicine. (Ex. 18, p. 1.) He maintains an active medical license in Rhode Island. (*Id.* at 2.) He currently works as a professor of psychiatry and neurology at Brown University, a staff neurologist and psychiatrist at Rhode Island Hospital, a neuropsychiatrist at Rode Island Hospital, a staff psychiatrist at Miriam Hospital, a staff physician at Providence Veterans Administration Medical Center, and a director of the Division of Neuropsychiatry and Behavioral Neurology at Rhode Island Hospital. (*Id.* at 3.) He has published over a 125 peer-reviewed articles, 6 books, and 29 book chapters. (*Id.* at 7-20.)

symptoms have persisted years after the 2015 injection." (*Id*.) He opines that petitioner meets the DSM-V diagnostic criteria for a somatic symptom disorder, which "consists of one or more somatic (bodily) symptoms that are distressing or result in significant disruption of daily life; excessive thoughts, feelings, or behaviors related to the somatic symptoms or associated health concerns; present persistently (typically more than 6 months)." (*Id*.) He notes that petitioner was first diagnosed as having a somatoform disorder (as per the prior DSM-IV) in 2006 and that she has subsequently had intermittent somatic presentations. (*Id.*) According to Dr. LaFrance, somatic symptom disorder is distinguished, not by the symptoms *per se*, but by how the symptoms present and how the patient interprets them. (*Id*.) The development of somatic symptom disorder is influenced by a number of factors, including genetic and biologic vulnerability (*e.g.*, increased sensitivity to pain), early traumatic experiences, learning, and cultural or societal norms that place greater weight or value on physical suffering as compared to psychological suffering. (*Id*.)

In his first report, Dr. LaFrance addresses each of the six parts of the *Loving* test for assessing significant aggravation claims in this Program.

Under the first three *Loving* prongs, a petitioner must show that a comparison between her pre- and post-vaccination condition represents a significant aggravation of her pre-existing condition. Dr. LaFrance indicates that petitioner had a prior history notable for the following symptoms: headaches, feet pain, dizziness, weakness, pain all over her body especially on her right side, shaking, confusion, and memory complaints. However, he stresses that, in the year prior to the vaccination at issue, petitioner had not been seen medically for any complaints of shooting pains or gait instability. (Ex. 17, pp. 32-33.) Regarding her post-vaccination condition, he explains that petitioner "described dizziness, headache and weakness the day of the 10/10/15 injection, which persisted, and in subsequent days, she reported developing debilitating symptoms, which interfered with daily activities, as noted in medical records and communications in 2016, 2017, and 2018." (*Id*. at 33.) Dr. LaFrance explains that petitioner's flu vaccine did not cause either her pre-existing somatic symptom disorder or fibromyalgia. However, he opines that her pre-existing somatic symptom disorder was significantly aggravated. He explains that petitioner has had several "time-limited" aggravations of her somatic symptom disorder (in 2012, 2014, and 2015) with periods of recovery in between. Prior to vaccination, she had experienced periods of recovery from prior episodes and "the decline since the 10/15 injection does not represent the natural course of her disorder." (*Id*.)

Regarding the fourth *Loving* prong – a medical theory of vaccine causation, Dr. LaFrance invokes the "fear-avoidance model." (Ex. 17, p. 33 (citing Johan W.S. Vlaeyen et al., *Fear of Movement/(Re)injury in Chronic Low Back Pain and Its Relation to Behavioral Performance*, 62 PAIN 363 (1995) (Ex. 21); W. Curt LaFrance Jr. & Helge Bjønæs, *Designing Treatment Plans Based on Etiology of Psychogeneic Nonepileptic Seizures*, *in* GATES AND ROWAN'S NONEPILEPTIC SEIZURES 283 (W. Curt LaFrance Jr. & Steven C. Schachter eds., 4th ed. 2018) (Ex. 22)).) According to Dr. LaFrance, this model explains that, for a somatic symptom disorder, a precipitating event is a

contributing factor in the causal chain of events for subsequent symptoms additional to the predisposing and perpetuating factors. Together, these three factors constitute the "3Ps." (*Id*. (citing W. Curt LaFrance Jr. & Orrin Devisnky, *Treatment of Nonepileptic Seizures*, 3 EPILEPSY & BEHAV. S19 (2002) (Ex. 23)).[14]) Applying this theory to petitioner's case under *Loving* prong five, Dr. LaFrance asserts that "the record demonstrates that symptoms (dizziness, headache and weakness) occurred the day of the 10/10/15 injection and increased and morphed (pain, paresthesias, gait imbalance) as time passed, post-injection, showing a logical sequence of cause and effect demonstrating that the injection worsened the pre-existing disorder." Dr. LaFrance asserts the timing of petitioner's significant aggravation is medically appropriate to infer causation; however, he does not explain the basis for that opinion. (*Id*.)

Dr. LaFrance indicates that petitioner's condition is unlikely to improve absent treatment for the predisposing and perpetuating factors contributing to her symptoms. However, he notes that this has not been done in this case. With treatment, she would have a guarded prognosis for some improvement; however, "[w]eighing against symptomatic improvement is that she had a grievance against the emergency department in 2015, which preceded the October 2015 flu injection, and also the amount of time she has gone untreated with targeted psychotherapy." (Ex. 17, p. 33.)

In his second report, Dr. LaFrance addresses in greater detail how to distinguish a precipitating event from a merely preceding event. (Ex. 34.) Dr. LaFrance acknowledged that accepting a preceding event as causal would be to accept the logical fallacy of "*post hoc ergo propter hoc*" (*i.e.*, "after this, therefore because of this"). (*Id*. at 1.) A precipitating event, by contrast, is "a specific event or trigger to the onset of current symptoms." He asserts that "[n]either a needle jab, nor a flu vaccine, are a cause by itself. The jab; however, in the context of predisposing, precipitating, and perpetuating factors, may be a link in the causal chain, for somatic symptoms . . . ." (*Id*.) The "3Ps" concept on which Dr. LaFrance relies originated in the context of post-traumatic symptoms. Under this concept, temperament and past history are predisposing, or predictive, factors of post-traumatic morbidity, precipitating events are specific triggering events, and perpetuating factors maintain dysfunction once established. (*Id*. at 2.) Dr. LaFrance cites examples from the literature involving anticipatory distress to painful medical procedures, insomnia, nonepileptic seizures, post-concussive symptoms, and chronic fatigue syndrome. (*Id*. (citing Nicole M. Racine et al., *Systematic Review: Predisposing, Precipitating, Perpetuating, and Present*

[14] In a subsequent order, I indicated that it was unclear how this article – which discusses precipitating events in the context of seizures – relates to this case. (ECF No. 54, n. 1.) In his second report, Dr. LaFrance explained that this article has been cited for its explanation of the "3Ps" concept – that is, predisposing, precipitating, and perpetuating factors. (Ex. 34, p. 2.) He explains that the seizures discussed in this paper are psychogenic non-epileptic seizures, which are also a form of somatic symptom disorder. (*Id*.) Dr. Dimsdale challenged this latter point, and Dr. LaFrance further stressed that non-epileptic seizures are categorized as a form of conversion disorder, which is in turn included among somatic symptoms disorders in the DSM-V. (Ex. 45, p. 2.) It should be noted, however, that conversion disorders are distinguished from other somatization disorders because they have an acute presentation that contrasts from the more chronic presentation of other somatization disorders. (Lesley A. Allen & Robert L. Woolfolk, *Cognitive Behavioral Therapy for Somatoform Disorders*, 33 PSYCHIATRIC CLINICS N. AM. 579 (2010) (Ex. 24).)

Factors Predicting Anticipatory Distress to Painful Medical Procedures in Children, 41 J. PEDIATRIC PSYCH. 159 (2016) (Ex. 41); Jason G. Ellis et al., *The Natural History of Insomnia: Predisposing, Precipitating, Coping, and Perpetuating Factors over the Early Development Course of Insomnia*, SLEEP, Sept. 2021, at 1 (Ex. 36); Markus Reuber et al., *Non-Epileptic Seizures and Other Functional Neurological Symptoms: Predisposing, Precipitating, and Perpetuating Factors*, 48 PSYCHOSOMATICS 230 (2007) (Ex. 42); Tyler A. Rickards, *Persistent Post-Concussive Symptoms: A Model of Predisposing, Precipitating, and Perpetuating Factors*, 29 APPLIED NEUROPSYCHOLOGY: ADULT 284 (2022) (Ex. 43); Kate Lievesley et al., *A Review of the Predisposing, Precipitating and Perpetuating Factors in Chronic Fatigue Syndrome in Children and Adolescents*, 34 CLINICAL PSYCHOLOGY REV. 233 (2014) (Ex. 39)).) He further notes that the World Health Organization has identified immunization anxiety as a cause of somatoform presentations in the form of what it calls "Immunization Stress Related Responses" or "ISRRs," which can include more immediate responses such as vasovagal responses, but also dissociative neurologic symptoms that can develop days after vaccination. (*Id.* at 3 (citing WORLD HEALTH ORG., CAUSALITY ASSESSMENT OF AN ADVERSE EVENT FOLLOWING IMMUNIZATION (AEFI): USER MANUAL FOR THE REVISED WHO CLASSIFICATION (2d ed. 2019) (Ex. 47)).)

Dr. LaFrance suggests that, practically speaking, this case boils down to an "eggshell" plaintiff type of scenario. (Ex. 34, p. 3.) He is critical of Dr. Dimsdale's conclusion that petitioner's condition is "in her imagination," noting that this could apply to all psychological disorders. (*Id*. at 4.) He states: "It is correct that there is no physical damage associated with the flu vaccine in this case, as noted by neurologist, Dr. Bromberg. It seems incorrect; however, to opine that a psychological impact from the jab, as benign as it is, was not a contributory factor to ongoing symptoms of her pre-existing symptoms, in this case." (*Id*.)

In his third and final report, Dr. LaFrance disagrees with Dr. Dimsdale's assertion that unusual or severe events are more likely to be precipitating events. Dr. Dimsdale cited the Holmes and Rahe Scale for rating stressful events, suggesting vaccination was a low stress event. In response, Dr. LaFrance stresses that this scale includes minor life events that can nonetheless be significant stressors (for example, Christmas or a vacation), "demonstrating that even regular, expected, common events can be stressors to specific people." (Ex. 45, p. 2.) Dr. LaFrance stresses that he is not opining that the flu vaccine caused petitioner's somatic symptom disorder. He explains that "[t]he claim is not that the shot *caused* the disorder, rather that the shot, as minor of an event as it is to many people, aggravated her pre-existing condition, as noted in her history and symptom pattern documentation before and after the injection." (*Id.*)

Dr. LaFrance cites two papers documenting four case reports of psychogenic gait disorders and an additional case of a psychogenic movement disorder following H1N1 influenza vaccination. (Ex. 45, pp. 2-3 (citing Jung Ho Ryu & Jong Sam Baik, *Psychogenic Gait Disorders After Mass School Vaccination of Influenza A*, 3 J. MOVEMENT DISORDERS 15 (2010) (Ex. 48); Chien-Yu Lin et al., Letter to the Editor, *Psychogenic Movement Disorders After H1N1 Influenza Vaccination*, 22 J.

NEUROPSYCHIATRY & CLINICAL NEUROSCIS., Summer 2011, at E37 (Ex. 49)).) He further cites case reports of somatic symptom disorders arising after Covid-19 vaccination. (*Id*. at 3 (citing Matthew Butler et al., *Functional Neurological Disorders After SARS-CoV-2 Vaccines: Two Case Reports and Discussion of Potential Public Health Implications*, 33 J. NEUROPSYCHIATRY & CLINICAL NEUROSCIENCES, Fall 2021, at 345 (Ex. 51); Tommaso Ercoli et al., *Functional Neurological Disorder After COVID-19 Vaccination*, 42 NEUROLOGICAL SCIS. 2989 (2021) (Ex. 52)).) Additionally, he cites a paper demonstrating that over 30% of placebo recipients (who thought they received the Covid-19 vaccination) suffered systemic adverse effects including headaches, fatigue, pain, tenderness, and diarrhea. (*Id*. at 3 (citing Julia W. Haas et al., *Frequency of Adverse Events in the Placebo Arms of COVID-19 Vaccine Trials: A Systematic Review and Meta-Analysis*, JAMA, Jan. 18, 2022, at 1 (Ex. 50)).) Finally, Dr. LaFrance cites two publications that he indicates specifically cite vaccination as among the possible precipitating events for somatic symptom disorders. (*Id*. (citing David Dongkyung Kim et al., *Helping the Public Understand Adverse Events Associated with COVID-19 Vaccinations: Lessons Learned from Functional Neurological Disorder*, 78 JAMA NEUROLOGY 789 (2021) (Ex. 53); Matt Butler et al., *Considerations for Causality Assessment of Neurological and Neuropsychiatric Complications of SARS-CoV-2 Vaccines: From Cerebral Venous Sinus Thrombosis to Functional Neurological Disorder*, 92 J. NEUROLOGY NEUROSURGERY & PSYCHIATRY 1144 (2021) (Ex. 54)).)

b. Respondent's expert, Joel Dimsdale, M.D.[15]

Dr. Dimsdale filed two reports. (Exs. A, E.) Dr. Dimsdale explains that

> [t]he record is abundantly clear that the patient was intensely focused on her symptoms, spending considerable time on the internet and in support groups, and doing literature searches. She developed a conviction about many illnesses and pressed her doctors for further tests. Some doctors described her as being 'fixated' on her conviction that her symptoms resulted from the flu shot.

(Ex. A, p. 28.) He notes that petitioner embellished her past medical history, exaggerated symptoms, rejected medications, and "[e]ven when tests came back as

[15] Dr. Dimsdale received his medical degree form Stanford University before completing a residency in psychiatry at Massachusetts General Hospital and a clinical fellowship in psychiatry at Harvard Medical School. (Ex. B, p. 1.) He is board certified by the American Board of Psychiatry and Neurology and maintains a medical license in California and Massachusetts. (*Id.*) He is currently employed as Regent Edwards A. Dickson Emeritus Professor and Distinguished Professor of Psychiatry Emeritus at the University of California, San Diego; an adjunct professor of psychology at San Diego State University; and a consultant to the Behavioral Medicine Branch of the National Heart, Lung, and Blood Institute. (*Id.* at 1-2.) Previously, Dr. Dimsdale was a member of the taskforce that wrote the DMS-V and chaired the somatic symptoms disorders workgroup of that taskforce, as well as the American Psychiatric Association Council of Psychosomatic Medicine. (*Id.*; Ex. A, p. 1.) He has published over 450 journal articles, as well as 43 chapter articles and non-refereed reports, 272 abstracts and meeting papers, 18 book reviews, and 9 books and monographs. (Ex. B, pp. 11-57.) Notably, Dr. Dimsdale was a section editor for somatic symptom disorders of UpToDate and authored chapters on such disorders in textbooks, such as The Comprehensive Textbook of Psychiatry and Merck Manual. (Ex. A, p. 1)

normal, she was not reassured and instead focused on findings that were of borderline significance." (*Id*.) When she was unable to persuade her doctors to attribute her somatic complaints to her vaccine, she changed doctors. (*Id*. at 28-29.) Dr. Dimsdale stresses that these behaviors are consistent with her prior medical history. For example, in 2006, she was diagnosed with a somatoform disorder after she persisted in reporting she had suffered a stroke, even after a complete work up had ruled out any stroke. (*Id*. at 29.) She was diagnosed with depression and anxiety in 2008 and 2011, respectively, and, even prior to vaccination, she reported many symptoms and her records reflect physician commentary that she was "very hypervigilant about her symptoms." (*Id*.) Dr. Dimsdale agrees with Dr. LaFrance that petitioner's primary diagnosis is somatic symptom disorder, which he further notes to be severe. (*Id*. at 30.) Especially given the extent of her history, he does not believe that petitioner's case represents malingering (*i.e.*, pursuing secondary gain in the form of compensation). (*Id*.) However, he disagrees with Dr. LaFrance's assessment of the role of petitioner's vaccination in her condition.

First, Dr. Dimsdale disagrees with Dr. LaFrance's assessment (under *Loving* prongs one and two) regarding petitioner's condition pre- and post-vaccination. Whereas Dr. LaFrance had suggested she had not been experiencing symptoms, namely shooting pains and gait instability, in the year prior to vaccination, Dr. Dimsdale stresses that she had an episode about four months prior to vaccination, in June of 2015, wherein she had attributed pain and memory loss to a steroid injection. He also stresses that at least some of petitioner's post-vaccination treatment records, such as an August 22, 2016 note by Dr. Gandingco, explained that "most of her symptoms pre-date the vaccination." In suspecting petitioner's symptoms were functional, he described the symptoms as having persisted ever since her "stroke" in 2006. (Ex. A, pp. 30-31.) Dr. Dimsdale does, however, "agree that she reported an enormous array of symptoms following the flu shot." (*Id*. at 31.)

Second, Dr. Dimsdale disagrees that petitioner's post-vaccination condition constitutes a "significant aggravation" of her prior condition. He opines that, given gaps in petitioner's treatment records and the lack of any psychosocial history, it is impossible to conclude that she ever recovered from the purported "stroke" episode documented in 2006. (Ex. A, p. 32.) He explains, "I don't think it is possible to conclude what the natural course of her disorder is, in the absence of such information. This is a disorder that fluctuates." (*Id*.) Although he agrees that petitioner experienced prior episodes of medically unexplained symptoms that were "briefer in duration," he does not think it is accurate to conclude that "medical interventions 'aggravated' her symptoms." (*Id*. at 32.) He explains that "[p]atients with somatic symptom disorders typically have a fluctuating course. There was nothing about the flu shot which led to her symptoms. Rather, she just thought that the symptoms were a consequence of the flu shot and fought off any disconfirming evidence from numerous treating physicians." (*Id*.) According to Dr. Dimsdale, "[t]he only thing that can be comfortably concluded is that the patient received an injection and in ensuing years developed multiple symptoms, many of which made no sense and were not supported by the numerous medical tests and examinations that were conducted by many physicians, including specialists." (*Id.*

at 31.) He notes that doctors repeatedly concluded that any connection between petitioner's vaccination and symptoms was coincidental. (*Id*.)

Third, Dr. Dimsdale disagrees with Dr. LaFrance's asserted theory of causation. Dr. Dimsdale agrees that the 3Ps (*i.e.*, predisposing, precipitating, and perpetuating factors) are useful as a heuristic framework, but he does not agree that they represent a causal chain as Dr. LaFrance asserts. (Ex. A, p. 33.) Instead, these factors simply result in vulnerability to somatic symptom disorder when they converge. While there are some instances in which a clear precipitant can be identified, it is often the case that precipitating factors are not identified. Therefore, precipitating events are not causally necessary, and it can be difficult to distinguish a precipitating event from a merely preceding event, even if the preceding event is a stressor. (*Id*.) Although the DSM-V has moved away from the term "hypochondria" to avoid stigmatizing patients, the concept remains causally important. (*Id*. at 30, 32-33.) Specifically, hypochondria involves a "health anxiety disorder." (*Id*. at 33.) It is anxiety-driven "catastrophizing" that causes patients to misattribute the meaning of their symptoms, commonly interpreting minor symptoms as harbingers of disaster. (*Id*. at 32-33.) In some instances, secondary issues such as deconditioning from inactivity or secondary gains (*e.g.*, being relieved of burdens by friends and family) can reinforce the patient's distorted view and create a vicious cycle. (*Id*. at 33.)

Fourth, Dr. Dimsdale disagrees with Dr. LaFrance's identification of a logical sequence of cause and effect implicating petitioner's vaccination in her condition. (Ex. A, pp. 33-34.) Dr. Dimsdale explains that knowing whether a given stressor is a "precipitating" versus merely a "preceding" event creates a definitional problem. People experience stressors daily. In attempting to deal with this issue, researchers rely on rating scales for stressful events to distinguish the profoundly disturbing from mere annoyances – for example, the death of a spouse would be rated as a greater source of stress than receiving a parking ticket. (*Id*. at 33.) Nonetheless, he acknowledges that, although there may be general consensus in rating the severity of the stress related to life events, the individual's own personal interpretation of the event is "enormously important." It is not the event itself, but the individuals' construal of the event, that leads to stress. (*Id*.) In this case, he asserts "there was no major stressful life event. The patient merely thought there was; she was mistaken." (*Id*. at 34.) And, although petitioner did report more symptoms as time went on, "the record also demonstrates that she was a poor historian – vague about important medical details (e.g. side effects of medications), inaccurate in reporting her medical history (e.g. repeatedly referring to having had strokes when the record indicates she was told she never had a stroke)." According to Dr. Dimsdale, what actually happened in this case is that petitioner had longstanding "strong expectations of harm from most medical interventions" and then "distorted information from medical staff to support her views." The flu vaccination was not a contributor to this process in any meaningful way (only "in her imagination"). (*Id*.)

In his second report, Dr. Dimsdale discussed the concept of precipitating factors in greater detail. (Ex. E.) Dr. Dimsdale explains that a "precipitating factor" is defined by the APA Dictionary of Psychology as a "particular factor, sometimes a traumatic or

stressful experience, that is the immediate cause of a mental or physical disorder. A single precipitating event may turn a latent condition into the manifest form of the disorder." (*Id*. at 1.) However, he identifies Dr. LaFrance's opinion – that the vaccination was a precipitant "because it was uniquely stressful to her, given her predisposing and perpetuating factors" – as problematic because it is an example of a non-falsifiable contention, which is inherently unscientific.[16] (*Id*. at 2.) Dr. Dimsdale explains that this problem requires researchers to weigh various stressful events differently. In that regard, the most commonly used tool for measuring stress is a rating scale created by Holmes and Rahe. (*Id*. (citing Thomas H. Holmes & Richard H. Rahe, *The Social Readjustment Rating Scale*, 11 J. PSYCHOSOMATIC RES. 213 (1967) (Ex. E-1)).) "With such criteria, one is on firmer ground testing whether a stressful precipitant occurred." (*Id*.) Based on the resulting research, Dr. Dimsdale asserts that "[t]he case for a precipitating stressor is strongest when it is an unusual and severe event (e.g. death of a spouse). . . . A flu shot voluntarily sought by the patient is not a major stressful life event." (*Id.*)

Upon review of the papers cited by Dr. LaFrance, Dr. Dimsdale questions their relevance, noting that they examined non-epileptic seizures (Exs. 37, 42), head trauma (Ex. 43), pain in children (Ex. 41), PTSD in firefighters (Ex. 40), chronic fatigue syndrome (Ex. 39), bus accidents (Ex. 38), and insomnia (Ex. 36). (Ex. E, pp. 3-4.) Further, he stresses that these papers do not strongly support the importance of stressful precipitating events. The studies involving insomnia and PTSD in firefighters in particular appear to have disclaimed any finding that precipitating events were an important variable. (*Id*.) According to Dr. Dimsdale's reading of the WHO Causality Assessment cited by Dr. LaFrance, the WHO would not causally attribute petitioner's condition to her vaccination precisely because she was already suffering a somatic symptom disorder prior to vaccination. (*Id*. at 4.)

V. Analysis

As explained above, the test for determining whether a vaccine has significantly aggravated a pre-existing condition is the six-part *Loving* test. In this case, I will first address general causation under *Loving* prong four – petitioner's medical theory explaining how a vaccine can in general aggravate the condition at issue. Under that analysis, although I recognize that functional symptoms occurring post-vaccination are a reported phenomenon, I find that petitioner has not preponderantly established that a vaccine can significantly aggravate a somatic symptom disorder. This could have been the end of the analysis; however, it is also important to observe that, even if accepting petitioner's theory *arguendo*, there would still be good reason to doubt that petitioner's own vaccination aggravated her condition based on her own clinical history. Turning to *Loving* prongs one through three, I explain why the facts of this case do not preponderantly support the assertion that what petitioner experienced was any aggravation of her somatic symptom disorder. Under *Loving* prong five, I further explain why, even though petitioner attributed her somatic complaints to her vaccination,

[16] To be clear, Dr. Dimsdale identifies this as a known, fundamental issue in the field of stress research, not a specific criticism of Dr. LaFrance. (Ex. E, p. 2.)

petitioner has not demonstrated a logical sequence of cause and effect implicating her vaccination as the cause of those complaints. Finally, under *Loving* prong six, I recognize that, had petitioner's expert been persuasive regarding the preceding five analytic prongs, the onset of petitioner's post-vaccination somatic complaints in this case is consistent with what her expert theorized.

a. *Loving* prong four

Petitioner's burden under the first *Althen* prong/fourth *Loving* prong is to provide, by preponderant evidence, "a medical theory causally connecting the vaccination and the injury." *Althen,* 418 F.3d at 1278. Such a theory must only be "legally probable, not medically or scientifically certain." *Knudsen*, 35 F.3d at 548-49. Moreover, scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs*., 569 F.3d 1367, 1380 (Fed. Cir. 2009). However, to satisfy this prong, petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen*, 35 F.3d at 548; *Boatmon*, 941 F.3d at 1359. Petitioner's burden under *Loving* prong four varies from her burden under *Althen* prong one in that a significant aggravation claim requires petitioner only to show that the vaccine at issue can worsen the condition at issue, rather than being its cause. *Sharpe v. Sec'y of Health & Human Servs.*, 964 F.3d 1072, 1083 (Fed. Cir. 2020) (explaining that "[u]nder *Loving* prong 4, a petitioner need only provide 'a medical theory causally connecting [petitioner]'s significantly worsened condition to the vaccination.'").

Under the DSM-V, "somatic symptom and related disorders" are a category of disorders that involve prominent somatic symptoms that cause significant distress and impairment. (AM. PSYCHIATRIC ASS'N, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS (5th ed. 2013) [hereinafter DSM-V] (Ex. 20, p. 1).) This categorization replaced the diagnosis of "somatoform disorder" from the DSM-IV. (*Id.*) "Somatic symptom disorder" is the primary disorder under this category of disorders. Others include conversion disorders and pseudocyesis. (*Id*.) In addition to better clarifying the conditions, the DSM-V sought to reduce the focus on unexplained medical symptoms. In particular, somatic symptom disorders may or may not accompany diagnosed medical disorders. (*Id*.) However, whereas unexplained symptoms still remain a key characteristic of conversion disorders and pseudocyesis, somatic symptom disorder is characterized by distressing somatic symptoms with abnormal thoughts, feelings, and behaviors in response to these symptoms, rather than by whether the symptoms are medically unexplained. (*Id*.)

In this case, petitioner has not alleged that any of her somatic symptoms were vaccine caused in themselves. (ECF No. 77, p. 1.) Instead, petitioner argues that the fact of the vaccination aggravated her underlying psychological condition, *i.e.*, acted upon petitioner's pre-existing somatic symptom disorder to trigger the attendant

abnormal thoughts and behaviors in response to symptoms.[17] (ECF No. 69, p. 43.) In order to explain how an event such as vaccination could be a triggering or precipitating event in the context of an ongoing somatic symptom disorder, Dr. LaFrance cites the fear avoidance model. According to Dr. LaFrance, this model supports the "3Ps" – predisposing, precipitating, and perpetuating factors – as combining to cause such disorders. However, based on my review of the literature that has been filed and the competing expert opinions, I find that Dr. Dimsdale is more persuasive in opining that, while valid as a heuristic, the "3Ps" do not establish precipitating factors as causes of somatic symptom disorders.

Although predisposing and perpetuating factors are important, the literature explaining somatic symptom disorders does not as a whole implicate triggering or precipitating events in the course of disorder. (DSM-V, *supra*, at Ex. 20, pp. 1-5; Lesley A. Allen & Robert L. Woolfolk, *Cognitive Behavioral Therapy for Somatoform Disorders*, 33 PSYCHIATRIC CLINICS N. AM. 579 (2010) (Ex. 24).) Somatic symptom disorders can arise spontaneously, and their causes can remain obscure, though they have high rates of comorbidity with anxiety and depressive disorders. (DSM-V, *supra*, at Ex. 20, pp. 1, 5.) While some somatic symptom disorder patients do experience "exacerbations" of their presenting symptoms when new interventions occur, this is part of the overall pattern of such patients finding that high levels of medical care utilization do not alleviate the symptoms. (*Id*. at 3.) In fact, somatic symptom disorder patients are at increased risk of iatrogenic illness due to disproportionate use and misuse of health care services. (Allen & Woolfolk, *supra*, at Ex. 24, p. 3.) By contrast, recognized "course modifiers" of the somatic symptom disorder itself focus on demographic features, history of abuse or chronic physical or psychologic illness, social stress, reinforcing social factors, and cognitive factors, but not specific triggering events. (DSM-V, *supra*, at Ex. 20, p. 4.) Instead, somatic symptom disorders involve ongoing anxiety regarding one's health that leads to a persistent and distressing focus on somatic symptoms. (*Id*. at 3.) The disproportionate focus on somatic symptoms, rather than the underlying reason for the somatic symptoms, is the primary feature of the disorder. The patient may or may not attribute their somatic symptoms to some other aspect of their lives and the symptoms may be normal bodily sensations. (*Id*. at 2.)

Consistent with this understanding of somatic symptom disorders, Dr. Dimsdale persuasively opines that, even as the DSM-V has moved away from terms such as hypochondria, somatic symptom disorders fundamentally remain a condition of ongoing health anxiety. (Ex. A, pp. 30, 32-33.) In that context, he opines that the underlying anxiety and catastrophizing by the patient is what explains the course of the condition. (*Id*.) As the literature cited by Dr. LaFrance similarly summarizes it: "A distinctive

[17] Temporary discomfort, whether in the form of arm soreness or more generalized constitutional symptoms, is not unusual following vaccination. However, it should be noted that, because somatic symptoms do not necessarily have to be medically unexplained to be implicated within a somatic symptom disorder (DSM-V, *supra*, at Ex. 20, p. 1), it is immaterial whether petitioner's initial report of weakness and headache the day after vaccination could plausibly have represented a transient vaccine reaction. The overall relationship between petitioner's vaccination and her somatic symptom disorder as discussed by the experts and throughout this decision is the same regardless of whether any of her initial symptoms might be attributed to her vaccination.

characteristic of many individuals with somatic symptom disorder is not the somatic symptoms per se, but instead the way they present and interpret them." (DSM-V, *supra*, at Ex. 20, p. 1.) Dr. LaFrance's focus on cognitive therapy as the determinant of petitioner's prognosis is also consistent with this understanding. (Ex. 17, p. 34.) That is, given this petitioner's own fluctuating history, Dr. LaFrance implicitly recognizes that the outward presentation of somatic symptoms does not neatly correlate with the presence of the disorder. Rather, "[v]ariations in symptom presentation are likely the result of the interaction of multiple factors within cultural contexts that affect how individuals identify and classify bodily sensations, perceive illness, and seek medical attention for them." (DSM-V, *supra*, at Ex. 20, p. 1.) It is the natural course for these types of conditions for symptoms to wax and wane and for new unexplained symptoms to arise over time. (Allen & Woolfolk, *supra*, at Ex. 24, p. 2.)

While the "3Ps" concept is a valid framework for understanding the various factors involved in some psychologic conditions, Dr. LaFrance's application of it as a *causal* concept to explain vaccine-aggravated somatic symptom disorder is weakly supported at best. Citing Vlaeyen et al., Dr. LaFrance grounds his reliance on the 3Ps in the fear-avoidance model, which was first explored with respect to fear of pain or reinjury in those suffering chronic musculoskeletal pain. However, the paper he cites regarding avoidance of chronic pain supports Dr. Dimsdale's explanation of anxiety-driven catastrophizing while also cautioning *against* assuming that precipitating events are causal. The authors explain:

> Several clinical disorders, such as hypochondriasis, are assumed to be reflective of catastrophizing cognitions in combination with a strong internal focus. A 3rd explanation could be that catastrophizing cognitions trigger unnecessary sympathetic arousal which results in the subjective feeling of anxiety. Of course, positive correlations may not be confused with causal effects. Catastrophizing can lead to increased fear, but the opposite might be true as well. Catastrophizing can also be part of the cognitive responses associated with fear of movement/(re)injury, or both may be related to a 3rd variable (e.g., a traumatic experience).

(Vlaeyen et al., *supra*, at Ex. 21, p. 7 (emphasis added) (internal citations omitted).)

Additionally, as Dr. Dimsdale points out, other studies cited by Dr. LaFrance likewise do not support precipitating events as causal. (Ex. E, pp. 3-4.) Specifically, Ellis et al. set out to examine whether the 3Ps concept was applicable to insomnia. (Ellis et al., *supra*, at Ex. 36.) Although they found that anxiety scores were higher among those with insomnia, there was no difference between insomnia patients and controls when applying a "Life Events Scale" to assess prior life experiences. (*Id*. at 8.) This appears to be more consistent with the above discussed understanding of somatic symptom disorders as broadly anxiety-driven than it is with Dr. LaFrance's theory of causation. McFarlane set out to examine the role of the 3Ps by following firefighters who had "extreme exposure" to a bushfire disaster. (Alexander C. McFarlane*, The Aetiology of Post-Traumatic Morbidity: Predisposing, Precipitating and Perpetuating*

Factors, 154 BRIT. J. PSYCHIATRY 221 (1989) (Ex. 40, p. 1).) The study found, contrary to its hypothesis, that "[n]euroticism and a past history of treatment for a psychological disorder were better predictors of post-traumatic morbidity than the degree of exposure to the disaster or the losses sustained. These results raise doubts about the postulated central aetiological role a traumatic event plays in the onset of morbidity." (*Id*.) Racine et al. examined the 3Ps with respect to anticipatory distress in children facing painful medical procedures. (Racine et al., *supra*, at Ex. 41.) The study identified two types of precipitating event: prior painful events and prior childhood behaviors. (*Id*. at 10.) However, the authors distinguished prior injections from other prior painful events. They noted that studies have shown a negative relationship between routine medical injections (such as insulin or immunotherapy) and anticipatory distress. (*Id*. at 18.)

It must also be noted that much of the literature Dr. LaFrance has cited is not directly on point. For example, although Dr. LaFrance has submitted a paper that identifies anxiety as frequently comorbid to chronic fatigue syndrome, that paper does not present chronic fatigue syndrome as a somatic symptom disorder. (Lievesley et al., *supra*, at Ex. 39.) He also cites literature discussing precipitating factors relative to head trauma (Ex. 43), PTSD in firefighters (Ex. 40), and a bus accident (Ex. 38). However, citing the Holmes and Rahe scale for measuring stressful events, Dr. Dimsdale explains that the case for labeling something as a precipitating factor is strongest when the event is unusual or severe. (Ex. E, p. 2.) Given that context, it is not readily apparent that observations related to trauma from bush firefighting, a bus accident, or head trauma, are informative of what occurs in the circumstance of a routine vaccination. Although Dr. LaFrance maintains that minor life events can be stressors under the Holmes and Rahe scale, he does not dispute the validity of the Holmes and Rahe scale or its relative ranking of differing stressful events. (Ex. 45, p. 2.) To the extent Dr. LaFrance contends that minor life events "can be stressors to specific people" (*Id.*), this caveat still tends to point to the features of the underlying somatic symptom disorder, rather than the nature of the purported triggering event, as the driving causal force that explains why a given individual will idiosyncratically interact with the minor event as a stressor.

Perhaps the most prominent example Dr. LaFrance cites for reliance on the 3Ps is non-epileptic seizures. (Ex. 17, p. 33 (citing LaFrance & Bjønæs, *supra*, at Ex. 22; LaFrance & Devisnky, *supra*, at Ex. 23).) In fact, Dr. LaFrance cites literature suggesting that non-epileptic seizures have been documented as occurring post-vaccination. (WORLD HEALTH ORG., *supra*, at Ex. 47, p. 62-63; Butler et al., *supra*, at Ex. 54, pp. 5-7.) Importantly, however, Dr. LaFrance acknowledges that non-epileptic seizures are conversion disorders. (Ex. 45, p. 2.) Dr. LaFrance suggests that, because conversion disorders are a form of somatic symptom disorder, they are merely "variations on a theme." (*Id*.) But this is not persuasive because the literature he has cited identifies critical distinctions between conversion disorders and somatic symptom disorders. First, "[t]he excessive thoughts, feelings, and behaviors characterizing somatic symptom disorder are often absent in conversion disorder." (DSM-V, *supra*, at Ex. 20, p. 13.) Second, it is specifically explained under the DSM-V, in contrast to somatic symptom disorder, that in conversion disorders "[o]nset may be associated with

stress or trauma, either psychological or physical in nature. The potential etiological relevance of this stress or trauma may be suggested by a close temporal relationship." (*Id*.) Third and relatedly, conversion disorders are known for having an acute presentation whereas somatic symptom disorders are generally chronic. (Allen & Woolfolk, *supra*, at Ex. 24, p. 4.) Accordingly, it is not clear that the phenomenon observed by this literature is generalizable to somatic symptom disorder. There appears to be a stronger basis for associating conversation disorders to specific stressors or triggers.

The literature cited by Dr. LaFrance does seem to support the proposition that post-vaccination conversion disorders are a recognized phenomenon in at least some circumstances.[18] (WORLD HEALTH ORG., *supra*, at Ex. 47, pp. 62-63; Butler et al., *supra*, at Ex. 54, pp. 5-7; Ryu & Baik, *supra*, at Ex. 48; Lin et al., *supra*, at Ex. 49; Ercoli et al., *supra*, at Ex. 52.) In that regard, Dr. LaFrance points out that the World Health Organization has concluded that immunization stress related responses – or ISRRs – are among adverse events that have a "consistent causal association to immunization." (WORLD HEALTH ORG., *supra*, at Ex. 47, p. 59.) The WHO defines ISRRs as "[adverse events following immunization] arising from anxiety about the immunization." (*Id.* at 16.) According to Dr. Dimsdale, however, a close reading of the WHO methodology for assessing causality distinguishes between acute stress-related responses to immunization (such as vasovagal syncope, *i.e*. fainting) on the one hand and anxiety-related dissociative neurological symptoms on the other hand. (Ex. E, p. 4; WORLD HEALTH ORG., *supra*, at Ex. 47, pp. 62-63.) In contrast to the former, the latter is specifically noted to have no apparent physiologic basis.[19] (WORLD HEALTH ORG., *supra*, at Ex. 47, pp. 62-63.) In either event, although the WHO categorizes ISRRs as consistently associated with immunization, nothing in the accompanying discussion identifies the *vaccination itself* as causal. (WORLD HEALTH ORG., *supra*, at Ex. 47, pp. 62-63.) Instead, the WHO identifies stress – which may involve biological factors combined with psychological factors and vulnerabilities within the specific social context – as causal. (*Id.* at 44.) Even to the extent the WHO acknowledges "triggering" factors, it characterizes the factors that may be triggering or may shape symptom manifestation as involving the "situations, circumstances" that surround the vaccination rather than the vaccination itself. (*Id.* at 63.) Thus, for example, these phenomena

[18] Because I find this literature to be distinguishable from the circumstances presented by this case, my analysis is limited to acknowledging that the cited literature does identify instances of post-vaccination functional neurologic disorders as Dr. LaFrance asserts. I do not reach the question of whether the literature is persuasive in presenting these observed disorders as vaccine caused.

[19] The WHO's identification of acute, transient physical stress response as the underlying cause of vasovagal syncopal reactions is consistent with the Vaccine Injury Table for this program, which includes vasovagal syncope as a Table Injury. (WORLD HEALTH ORG., *supra*, at Ex. 47, p. 62; 42 C.F.R. § 100.3(a).) The WHO also indicates that "dissociative neurological symptom reaction," including non-epileptic seizures and weakness or gait difficulties, can arise post-vaccination. (WORLD HEALTH ORG., *supra*, at Ex. 47, pp. 62-63.) Consistent with that, petitioner has filed several publications observing post-vaccination functional neurologic disorders, primarily case reports involving temporary gait abnormalities in children. (Butler et al., *supra*, at Ex. 54, Ryu & Baik, *supra*, at Ex. 48, Lin et al., *supra*, at Ex. 49, Ercoli et al., *supra*, at Ex. 52.) However, the WHO assessment in particular focuses on non-epileptic seizures, which, as discussed above, Dr. LaFrance has identified as a form of conversion disorder.

often arise in the context of mass immunization. In that context, the spread of the condition within the immunized population is explained by mass psychogenic illness due to witnessing others having what are perceived to be vaccine reactions, rather than one's own initial physiologic response to vaccination. (*Id.* at 44-45; Butler et al., *supra*, at Ex. 54, p. 6.) Ultimately, because the WHO methodology for assessing causality in a given case requires considering, among other things, pre-existing illness, and because the WHO focuses causality on the factors affecting stress and anxiety, Dr. Dimsdale is persuasive in observing that the WHO causal assessment does not readily implicate a vaccine as the cause of symptoms otherwise attributable to the anxiety related to an ongoing somatic symptom disorder as opposed to the type of *de novo* conversion disorder cited within the publication. (Butler et al., *supra*, at Ex. 54, p. 6; *see also* WORLD HEALTH ORG., *supra*, at Ex. 47, pp. 25, 36 tbl.1.)

Thus, for all of the reasons discussed above, petitioner has not presented a preponderantly supported theory demonstrating that a vaccination can be a substantial contributing factor in the significant aggravation of an ongoing somatic symptom disorder. Therefore, petitioner has failed to meet her burden of proof under *Loving* prong four.

b. *Loving* prongs one through three

Under the Vaccine Act, a "significant aggravation" of a condition is "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." § 300aa-33(4). In order to assess when this has occurred, the first three *Loving* prongs examine (1) the vaccinee's condition prior to the administration of the vaccine and (2) the vaccinee's current condition, and then (3) assess whether a comparison of the pre- and post-vaccination conditions constitutes a "significant aggravation" of the condition. *W.C.*, 704 F.3d at 1357. Although petitioner need not prove the expected outcome of her pre-vaccination condition or that her post-vaccination condition is worse than the expected outcome, petitioner still must show that her post-vaccination condition was affected by his vaccination. *Locane v. Sec'y of Health & Human Servs.*, 685 F.3d 1375, 1381 (Fed. Cir. 2012); *Sharpe v. Sec'y of Health & Human Servs.*, 964 F.3d 1072, 1082 (Fed. Cir. 2020).

i. *Loving* prong one

Regarding *Loving* prong one, both parties' experts agree that petitioner suffered an ongoing course of somatic symptom disorder first diagnosed in 2006. (Ex. 17, p. 32; Ex. A, p. 29.) The experts further agree that, by the time of the vaccination at issue, petitioner had an established pattern of misattributing symptoms to medical events and procedures. (Ex. 34, p. 3; Ex. A, p. 31.)

Although Dr. LaFrance seeks to suggest petitioner was essentially free of relevant complaints in the year preceding her vaccination, he focuses only on reported symptoms of shooting pains or gait instability. (Ex. 17, pp. 32-33.) Overall, Dr.

Dimsdale persuasively opines that, especially in the absence of any psychosocial evaluation, petitioner's medical records are inadequate to conclude that she was experiencing any relief from her somatic symptom disorder prior to the vaccination at issue. (Ex. A, p. 32.) While Dr. LaFrance urges that petitioner experienced periods of seeming recovery (Ex. 17, p. 33), this is not incompatible with the known fluctuating presentation of somatic symptom disorders broadly (DSM-V, *supra*, at Ex. 20, p. 3; Allen & Woolfolk, *supra*, at Ex. 24, p. 2). However, it is inconsistent with Dr. LaFrance's explanation of petitioner's prognosis. Despite fluctuations, Dr. LaFrance opined that petitioner's condition would not actually improve without treatment, which he agreed she had never received. (Ex. 17, p. 34.)

Thus, the evidence preponderates in favor of a finding under *Loving* prong one that prior to vaccination petitioner had been experiencing a nine-year history of somatic symptom disorder that included periodic episodes of misattributing somatic symptoms to unrelated medical events and procedures. Although petitioner's medical records reflect less activity vis-à-vis potential somatoform symptoms just prior to the time of her vaccination, the evidence does not preponderant in favor of a finding that she was within a period of recovery from her somatic symptom disorder at the time of vaccination.

ii. *Loving* prong two

Regarding *Loving* prong two, there is no dispute between the experts that petitioner began complaining of new symptoms post-vaccination that she misattributed to her flu vaccine. (Ex. 34, p. 3; Ex. A, p. 32.) However, these were subjective complaints, and Dr. Dimsdale is persuasive in asserting that petitioner was not a reliable historian. (Ex. A, pp. 31, 34; Ex. E, p. 2.) Moreover, there is no dispute that these reported symptoms lacked any organic basis and that they were a consequence of her ongoing somatic symptom disorder. (Ex. 34, pp. 3-4; Ex. 45, p. 2; Ex. A, p. 34; Ex. E, p. 2.) Although petitioner's post-vaccination episode was more extensive than prior episodes, her misattribution of symptoms to her flu vaccination was consistent with her established prior pattern of misattribution.

iii. *Loving* prong three

Comparing petitioner's pre- and post-vaccination conditions under *Loving* prong three, Dr. LaFrance in effect concludes that because petitioner experienced her most extensive episode of somatic symptoms and misattribution post-vaccination, her condition necessarily had worsened following the vaccination. (Ex. 17, p. 33.) He specifically opined that petitioner's post-vaccination presentation was not the natural course of her condition. (*Id.*) Dr. Dimsdale disagrees. He explains that petitioner's reporting of symptoms post-vaccination was never accurate. (Ex. A, p. 34.) Accordingly, these reported symptoms do not in themselves represent a significant aggravation of the somatic symptom disorder. Dr. Dimsdale opines that what petitioner experienced post-vaccination was one episode of somatic symptom misattribution consistent with her overall history of such episodes. (Ex. E, p. 2.) He explains that

somatic symptom disorders do generally have a fluctuating course as petitioner has demonstrated. (*Id.*; Ex. A, p. 32.) I am persuaded by Dr. Dimsdale's opinion.

Petitioner is clear in her motion for a ruling on the record that the condition she contends was aggravated was the somatic symptom disorder itself. (ECF No. 69, p. 43.) "Petitioner does not claim that her 'subjective and somatic complaints regarding her flu vaccination' are her vaccine injury . . . ." (ECF No. 77, p. 1.) In that regard, Dr. LaFrance also confirms in his reports that he is not opining that the flu vaccine *per se* caused petitioner's reported symptoms. (Ex. 34, p. 1; Ex. 45, p. 2.) However, in arguing she has satisfied *Loving* prong three, petitioner focuses on the fact that there was a change in the frequency and severity of the subjective symptoms she reported post-vaccination. (ECF No. 69, pp. 55-56.) Specifically, petitioner argues that the worsening of her condition is evidenced

> among other things, [by] her increased and disproportionate perseveration on her somatic symptoms and the flu vaccine being a cause as a substantial factor, increased doctor visits, increased embellishment of health history, more severe and debilitating reported somatic symptoms, changes in behavior (e.g., climbing stairs by crawling backwards or inability to stand long enough to cook) that comport with reported increases in somatic symptom severity and accompanying impairment, and increased anxiety about her health and symptoms.

(Ex. 77, p. 3.) Yet, petitioner has not substantiated that these changes in presentation indicate petitioner's somatic symptom disorder was worse.

Although somatic symptoms are obviously a key feature of somatic symptom disorder, unexplained symptoms are not sufficient to make a diagnosis of somatic symptom disorder. (DSM-V, *supra*, at Ex. 20, p. 2.) As explained under *Loving* prong four,

> [a] distinctive characteristic of many individuals with somatic symptom disorder is not the somatic symptoms per se, but instead the way they present and interpret them. Incorporating affective, cognitive, and behavioral components into the criteria for somatic symptom disorder provides a more comprehensive and accurate reflection of the true clinical picture than can be achieved by assessing the somatic complaints alone.

(*Id*. at 1.) There is some evidence to suggest that the number of somatic symptoms reported correlates positively to the degree of psychological distress being experienced (Allen & Woolfolk, *supra*, at Ex. 24, p. 3); however, "[t]he course of somatization disorder tends to be characterized by symptoms that wax and wane, remitting only to return later or be replaced by new unexplained physical symptoms. Thus, somatization disorder is a chronic, polysymptomatic disorder whose requisite symptoms need not be manifested concurrently" (*Id*. at 2). Therefore, petitioner has not substantiated that the mere fact that she was experiencing an episode of somatic symptoms that she actively

misattributed to her flu vaccine indicates that the mental state underlying her somatic symptom disorder had actually changed or worsened.

Petitioner's reporting of subjective complaints did increase post-vaccination. However, even while accepting that somatic complaints represent genuine suffering, petitioner's limitations as a historian indicate that these complaints were not necessarily reliable, as Dr. Dimsdale explains.[20] Moreover, the specific pattern of her complaints is not explained by her disorder alone. Dr. Dimsdale has explained that a feature of petitioner's condition is active resistance to confounding medical information. (Ex. A, pp. 31-33.) Aspects of her clinical history, such as increased doctor visits and embellishment of her history, may speak to the level of resistance she received while interacting with her treaters as much or more so than the fundamentals of her condition. (*Accord* Allen & Woolfolk, *supra*, at Ex. 24, p. 3 (explaining that "[t]hese patients disproportionately use and misuse health care services. When standard diagnostic evaluations fail to uncover organic pathology, patients with somatization tend to seek additional medical procedures, often from several different physicians.").) And, in any event, somatic symptom disorders are known to fluctuate. (DSM-V, *supra*, at Ex. 20, p. 3; Allen & Woolfolk, *supra*, at Ex. 24, p. 2.) Overall, petitioner's post-vaccination behavior was consistent with the previously established pattern of her own somatic symptom disorder. That is, her pattern of symptom presentation and attribution both before and after vaccination demonstrates a consistent way of interpretating her symptoms within the context of a somatic symptom disorder. Therefore, Dr. Dimsdale is persuasive in opining that what petitioner has experienced is a continuous yearslong course of a severe somatic symptom disorder that was ongoing both before and after vaccination. (Ex. A, p. 34; Ex. E, p. 2.) Consistent with that opinion, Dr. LaFrance likewise noted that petitioner was first diagnosed with somatic symptom disorder in 2006, had multiple subsequent episodes, and would not have improved without targeted psychotherapy treatment, which he acknowledged she had not received. (Ex. 17, pp. 32-34.)

For all these reasons, even if petitioner had successfully demonstrated that a stressful trigger event can theoretically aggravate a somatic symptom disorder, petitioner has not demonstrated that she herself suffered a significant aggravation of her somatic symptom disorder. This conclusion is consistent with *Locane*, 685 F.3d 1375. I am not requiring petitioner to demonstrate that the actual course of her condition is worse than otherwise would have been expected. *See Sharpe*, 964 F.3d 1072. Nor am I requiring petitioner to prove that her post-vaccination condition is not explained by her preexisting condition. *Id*. Rather, I have concluded that petitioner has failed to

[20] In her reply, petitioner argues that it is irrelevant whether her complaints were credible because increased embellishment of her medical history is part of the basis for concluding that her somatic symptom disorder had worsened. (ECF No. 77, pp. 3-4.) This is not an entirely unreasonable point, but it ultimately presents a conundrum. While embellishment of her medical history may be consistent with her somatic symptom disorder, it is still admitted embellishment that makes it more difficult to accept the medical records at face value with respect to any subjective symptom. Because petitioner bears the burden of proof regarding the factual question of whether her condition worsened, and because no organic cause is available to correlate or confirm her reported symptoms, the consequences of this conundrum fall on petitioner to resolve, if resolution is even possible.

distinguish her post-vaccination episode of somatic symptom complaints from her overall pattern of such episodes, which otherwise constitute the natural, fluctuating course of her ongoing somatic symptom disorder. In other words, the outward presentation of petitioner's complaints of somatic symptoms is not coextensive with her psychologic state and petitioner has not demonstrated that her psychological condition – which is the condition that underlies her claim – actually worsened post-vaccination. Although this is a distinct analysis from the analysis under *Loving* prong five, the *Loving* prong five analysis also further explains why petitioner's vaccination did not affect her condition.

c. *Loving* prong five

The second *Althen* prong/fifth *Loving* prong requires proof of a logical sequence of cause and effect showing that the vaccine was the reason for the injury, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1317, 1326; *Grant*, 956 F.2d at 1148. However, medical records and/or statements of a treating physician do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. *See* 42 U.S.C. §300aa-13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 745 n.67 (2009) (stating that "there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct – that it must be accepted in its entirety and cannot be rebutted"). The special master is required to consider all the relevant evidence of record, draw plausible inferences and articulate a rational basis for the decision. *Winkler v. Sec'y of Health & Human Servs.*, 88 F.4th 958, 963 (Fed. Cir. 2023) (citing *Hines*, 940 F.2d at 1528).

Petitioner's medical records reflect that her treating physicians largely focused on addressing petitioner's assertions of vaccine-causation in the context of whether her symptoms had any organic basis. To the extent some of the treating physicians did recognize that petitioner's presentation was consistent with a somatic symptom disorder, they did not opine that petitioner's condition was caused by her vaccination despite acknowledging that she attributed her symptoms to the vaccination. That leaves petitioner's claim dependent on the opinion of her expert. Dr. LaFrance contends that petitioner experienced her vaccination as a stressful event that triggered her underlying vulnerability to cause her to experience psychosomatic effects of the vaccination. (Ex. 34, pp. 1-4.) This line of reasoning contemplates that petitioner's somatic symptom disorder had been in some form of stasis, that her vaccination then produced a new anxiety, and that this anxiety led to her increased symptoms. As a threshold matter, this premise is not well supported as a matter of clinical history for the reasons discussed under *Loving* prongs one through three, above. Furthermore, and consistent with the discussion of the nature of somatic symptoms disorders under *Loving* prong four above, Dr. Dimsdale is also persuasive in essentially indicating as a further matter that Dr. LaFrance has the sequence of cause and effect backward.

Dr. LaFrance suggests that a vaccination could theoretically be anxiety inducing and that this anxiety could in turn result in somatic symptoms. However, there is no evidence to suggest that this is what actually happened in this case. Nothing in the record suggests that petitioner suffered any particular apprehension or anxiety regarding her vaccination. Rather, petitioner received the vaccination voluntarily and, as Dr. Dimsdale suggested, vaccination would be exceptionally low on the Holmes and Rahe scale of stressful events. (Ex. A, pp. 33-34; Ex. E, p. 2.) Nor, despite her ongoing somatic symptom disorder, is there any evidence that petitioner had any prior vaccine hesitancy. In fact, as respondent stresses, petitioner had a history of receiving vaccinations without issues. (ECF No. 75, p. 45 (citing Ex. 2, p. 5).) Instead, the medical records confirm that petitioner simply suffered a somatic symptom disorder and general ongoing anxiety and depression, all of which were diagnosed pre-vaccination. If anything, Dr. LaFrance suggests that the record reflects that petitioner's ongoing anxiety around the time of vaccination may have been related to a separate grievance relating to a prior emergency department visit. (Ex. 17, p. 34.) Specifically, he identified petitioner's reported grievance against the emergency department noted in January of 2015 as a relevant course modifier that would weigh against any prognosis for improvement in her somatic symptom disorder. (*Id.*)

Thus, rather than the vaccination being a precipitating event, it is more likely, as Dr. Dimsdale explains, that the vaccine was merely a preceding event that then became an object of petitioner's fixation as a result of her somatic symptom disorder. (Ex. E, pp. 2, 4.) As previously explained, Dr. Dimsdale indicates that somatic symptom disorders operate as anxiety disorders. (Ex. A, p. 33.) Although petitioner's symptoms are real despite lacking an organic cause, they are caused by her ongoing anxiety. (*Id.* at 33-34.) Thus, according to Dr. Dimsdale, it is not that the flu vaccine caused anything, it is that petitioner's somatic symptom disorder caused her to fixate on the vaccination as a perceived explanation for her somatic symptoms which, in turn, had been caused by her underlying anxiety. (*Id.*) That is, to the extent there is any causal chain at all, the flu vaccine is the end of the chain, not it's beginning.

This reasoning is illustrated by petitioner's prior established pattern of behavior. For example, petitioner had a prior history of repeatedly attributing many symptoms to a stroke. However, her physicians came to the conclusion that petitioner had never actually suffered any stroke. Therefore, it would be impossible to assemble a sequence of cause and effect that implicated a stroke as a cause of either petitioner's symptoms or her mental state. The idea of a stroke became an object of fixation as a consequence of her condition; however, there was no stroke that could have served as the beginning of any causal chain. There is no basis on this record for supposing that any different dynamic applies to the fact of petitioner's vaccination. Indeed, Dr. LaFrance has himself cited literature confirming that anxiety and depression alone can cause somatic symptoms and that somatic symptoms can also occur spontaneously. (DSM-V, *supra*, at Ex. 20, p. 1.) Accordingly, it is patently *not* the case that petitioner's presentation requires an explanatory trigger.

For these reasons, petitioner has failed to preponderantly establish a logical sequence of cause and effect suggesting that her flu vaccination significantly aggravated her somatic symptom disorder.

d. *Loving* prong six

The third *Althen* prong/sixth *Loving* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury. *Id.*; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd per curiam*, 503 Fed. App'x 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877, at *26 (Fed. Cl. Spec. Mstr. May 30, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

Petitioner called her primary care provider the day after her vaccination to complain about new symptoms of dizziness, headache, generalized weakness, and fluctuating vision. (Ex. 2, p. 1696.) This timing is consistent with what Dr. LaFrance has theorized. Specifically, the WHO causality assessment cited by Dr. LaFrance indicates that ISRRs, including the non-epileptic seizures cited by Dr. LaFrance as an example of a conversion disorder, can occur within hours to days of vaccination. (WORLD HEALTH ORG., *supra*, at Ex. 47, pp. 62-63.) Dr. LaFrance also cited a paper featuring four case reports of post-H1N1 vaccination psychogenic gait disorders that arose between hours to 14 days post-vaccination. (Ryu & Baik, *supra*, at Ex. 48, p. 2 tbl.1.) However, because petitioner has not met her burden of proof with respect to *Loving* prongs three, four, or five, this is effectively immaterial. These preceding analyses establish that the vaccination was merely a preceding, rather than precipitating, event.

Dr. LaFrance acknowledges that ascribing causation to a merely preceding event would be a logical fallacy – *post hoc ergo propter hoc*. (Ex. 34, p. 1.) This is also consistent with well-established program precedent. *Veryzer v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 344, 356 (2011) (explaining that a "temporal relationship alone will not demonstrate the requisite causal link and that petitioner must posit a medical theory causally connecting the vaccine and injury"), *aff'd per curiam*, 475 Fed. App'x 765 (Fed. Cir. 2012); *Hibbard v. Sec'y of Health & Human Servs.*, 698 F.3d 1355, 1364-65 (Fed. Cir. 2012) (holding the special master did not err in resolving the case pursuant to *Althen* prong two when respondent conceded that petitioner met *Althen* prong three).

VI. Conclusion

I am mindful of the fact that petitioner's condition is genuine and her suffering is very real. Nothing in this decision is intended to minimize petitioner's suffering or the impact her condition has had on her life. However, for all the reasons discussed above, I cannot conclude that petitioner has demonstrated any causal role for her October 10, 2015 flu vaccine either as a cause of any of her symptoms or as a cause of any significant aggravation of her underlying somatic symptom disorder. Therefore, this case is dismissed.[21]

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master

[21] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.